

Approved 3-21-89
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by SENATOR ROY M. EHRLICH at
Chairperson

10:00 a.m./~~p.m.~~ on March 15, 1989 in room 526-S of the Capitol.

All members were present except:

Committee staff present:

Emalene Correll, Legislative Research
Bill Wolff, Legislative Research
Norman Furse, Revisors Office
Clarene Wilms, Committee Secretary

Conferees appearing before the committee:

Joe Siemens, Administrator, American Red Cross, Wichita Regional Blood Services, Wichita, Kansas
Jane Mackey, President, Topeka Blood Bank
Teresa Hodges, Director, Laboratory Certification & Improvement, KDHE
Marla Williams, M.T., (ASCP), Supervisor, Immunochemistry Dept., Stormont Vail Regional Medical Center Laboratory, Topeka, Kansas
Tim Madden, Department of Corrections
Lila Pasley, Chairperson, Legislative Affairs, Association For Retarded Citizens of Kansas, Inc.

The chairman called the meeting to order and requested the wishes of the committee concerning the minutes of February 27, February 27 II, March 1, March 2, 3 and 6, 1989.

Senator Hayden moved to accept the minutes as presented. Senator Walker seconded the motion and the motion carried.

Senator Kanan introduced his two granddaughters who were serving as pages, Destiny Lorange and Courtney Martin. Senator Ehrlich introduced Adrienne Tobias who was serving as his page.

Joe Siemens, Administrator of American Red Cross, Wichita Regional Blood Services, Wichita, appeared in support of HB-2327 stating that the current law excludes blood banks from being classified as laboratories and from additional regulation by the State Department of Health and Environment. Therefore blood bank laboratories cannot perform HIV testing as a reference laboratory for physician offices or hospitals and cannot receive compensation for that service. This exclusion affects the cost of services provided and also restrains availability of service to many communities through the state. Passage of HB-2327 would benefit all of the physicians and patients in Kansas. (Attachment 1)

Jane Mackey, President, Topeka Blood Bank, appeared before the committee in support of HB-2327 stating that this bill would provide blood banks the opportunity to be considered a "laboratory" and regulated with the Secretary of Health and Environment when extending human immuno-deficiency virus testing services to the medical community. Ms. Mackey stated that passage of HB-2327 would permit blood banks to be reviewed and regulated as laboratories in order to perform HIV testing that would qualify for reimbursement by third party payers. She further stated that this is a highly utilized service and if not partially provided by the blood banking community, could create inconveniences for physicians and individuals desiring testing. Inspection could be done at the time the state inspects facilities for Medicare. (Attachment 2)

Theresa L. Hodges, Division of Laboratories and Research, KDHE, appeared in support of blood banks and tissue banks who desire to be included in the approval process set out in HB-2327. She further stated that any exemptions to the requirements for approval would seriously weaken the

CONTINUATION SHEET

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

room 526-S, Statehouse, at 10:00 a.m./~~p.m.~~ on March 15, 1989.
intent of the statute, which is to provide assurance of quality test results. (Attachment 3)

Marla Williams, Supervisor, Immunochemistry Dept., Stormont-Vail Regional Medical Center Laboratory, spoke in support of the deletions proposed in SB-2327 stating she and fellow laboratorians and Dr. Hiszczyjnyj urged the removal of the entire exclusion clause. Ms. Williams further stated she believed quality should not be sacrificed for cost concerns. (Attachment 4)

Tim Madden, Department of Corrections, appeared before the committee requesting the Department of Corrections be exempted from HB-2327 due to the fact that the DOC utilizes "in house" drug testing. Mr. Madden stated "in house" testing is used in the institutional setting where there are no constitutional rights. Quick test results are often needed to make rapid decisions involving management of prisoners. Such tests are not used for parolees as they have greater "due process" rights. Senator Walker asked if the facilities would not pass inspection standards and Mr. Madden stated that the tests now being performed are much less expensive than the ones the laboratories use and which would involve inspection standards. Ms. Hodges, KDHE, stated there is a statute, 65-1108 (b) which has a provision that says any person or laboratory who performs tests and is not approved is guilty of a misdemeanor. Mr. Madden stated they were requesting exemption for only one kind of testing, that of urinalysis, and only for testing inmates. He pointed out that tests used for urinalysis have been litigated in the courts and have been found to be valid throughout the United States when used in the correctional setting. Ms. Hodges stated the Department of Corrections would have difficulty in meeting another qualification, that of a Ph.D. or physician overseeing the lab, also positive tests would have to be confirmed. During discussion with the Department of Corrections it appeared that when tests are used for strictly management purposes the "in house" test would be sufficient. However, if due process is involved the person deserves full testing.

Senator Reilly will investigate this situation further and report back to the committee.

Lila Paslay, Association for Retarded Citizens of Kansas appeared in support of HB-2206. Ms. Paslay stated that more individuals with mental retardation are being served in community facilities and the possibility of abuse and/or neglect is increased. Therefore, the protection provided in this bill would, hopefully, give assurance that cases of abuse and/or neglect would not go unreported and would insure improved care and safety. It was also stated that there was concern about the transferring of monitoring to the Department of Health and Environment. However, it was felt by the Association for Retarded Citizens that SRS would be the appropriate monitoring agency and the association desired to have this issue addressed. (Attachment 5)

Written testimony was presented by the Kansas Association of Rehabilitation Facilities stating support for HB-2206 as amended by the House. This bill would make the reporting process mandatory and the policies established by KARF regarding abuse and neglect would be included. (Attachment 6)

Written testimony by Gary H. Blumenthal, sponsor of the bill, was handed to committee members. Representative Blumenthal stated HB-2206 simply amends Kansas' abuse reporting statute, adding community mental retardation facilities and residential facilities to those that must report suspected cases of abuse. (Attachment 7)

Senator Burke moved, with a second from Senator Langworthy, to pass out HB-2206 Favorable for passage. The motion carried.

The meeting adjourned at 10:50 a.m. and will convene at 10:00 a.m. on Thursday, March 16, 1989.

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE

DATE March 15, 1989

(PLEASE PRINT)
NAME AND ADDRESS

ORGANIZATION

JANE MACKAY, P.O. Box 517

TOPEKA BLOOD BANK

Wichita Ks 67203
JOE SIEMENS 707 N MAIN

American Red Cross
WICHITA REGIONAL BLOOD SER.

Theresa Hodges Topeka

Ks. Dept. of Health + Environ.

Timothy G. Madden

Ks Dept of Corrections

~~Timothy G. Madden~~
Allen Parker Topeka

S.R.S.

Marion Finney Topeka

SLS Adult Serv.

M. Hawver "

Cap-Journal

Ken Bahr Topeka

Ks. Society of Lab. Tech.

Marla Williams Topeka

Stromont-Vail RMC Lab
CHRISTIAN SCIENCE COMMITTEE
ON PUBLICATION FOR KANSAS

KEITH R LANDIS "

KMS

Jerry Gaudin Topeka

John Stutz Topeka

Ks. Soc. to Prom. Technol.

Sue Paslay

ARC/Kansas



Blood Services
Wichita Region
707 N. Main
Wichita, Kansas 67203-3669
(316) 265-6601

Testimony on House Bill No. 2327
15 March 1989

Chairman Ehrlich and members of the Committee on Public Health and Welfare, I am Joe Siemens, Administrator of American Red Cross, Wichita Regional Blood Services in Wichita, Kansas.

The Wichita Region encompasses 84 counties in Kansas and services 111 hospitals in those counties. I am here today in support of House Bill No. 2327, a bill which allows blood banks to be regulated by the Secretary of Health and Environment when performing HIV (human immunodeficiency virus) testing services for the medical community.

The current law, as it exists, excludes blood banks from being classified as laboratories and from additional regulation by the State Department of Health and Environment. In doing so, blood bank laboratories cannot perform HIV testing as a reference laboratory for physician offices or hospitals and cannot receive compensation for that service. This not only affects the cost of services provided, but restrains the availability of service to many communities throughout the state. A number of small rural communities lack the expertise and resources necessary to perform this highly technical test. American Red Cross is not seeking additional regulation, but is willing to submit to regulation in order to provide this service.

Testimony on House Bill 2327
American Red Cross
15 March 1989
Page 2

Since the beginning of HIV testing in 1985, Wichita Regional Blood Services has provided testing service to physicians and hospitals as an alternative to people donating blood to learn of their HIV antibody status. Since 1985, 369,237 HIV tests have been performed on donated units of blood. During 1988, 636 tests were performed for other than donor blood analysis. This volume exceeds most other laboratories in the state. Wichita Regional Blood Services HIV testing proficiency is monitored by the College of American Pathologists and is inspected annually by the Food and Drug Administration. Due to the sheer volume and testing requirements, there are no other laboratories in Kansas more qualified to be doing HIV testing.

Your support of House Bill No. 2327 is requested so that all of the physicians and patients in Kansas can benefit from the services available in community blood banks.



TOPEKA BLOOD BANK

March 15, 1989

Chairman Ehrlich and members of the Senate Public Health and Welfare Committee, my name is Jane Mackey and I am the President of Topeka Blood Bank in Topeka, Kansas. I appear before you today in support of House Bill No. 2327, a bill which will provide blood banks the opportunity to be considered a "laboratory" and regulated by the secretary of health and environment when extending human immunodeficiency virus (AIDS) testing services to the medical community.

In March, 1985, the HIV test was approved by the Food and Drug Administration to screen the blood supply. We extended our testing services to area physicians and hospitals to keep high risk individuals from donating blood to learn of their HIV antibody status.

Since that time we have performed over 60,000 tests on each unit of blood that is donated and on patient samples from hospitals and local physicians. During 1988 we tested over 1,000 outpatient samples for HIV. Our volume of testing exceeds most area labs. Our proficiency is monitored by our required participation in the College of American Pathologists staff proficiency testing for HIV, a national test providing quarterly samples for evaluation. In addition, we are inspected annually by Medicare, the American Association of Blood Banks, and the Food and Drug Administration.

Patient confidentiality is maintained by assigning numbers to the samples to be tested rather than names. The test results are reported back to the prescribing physician for patient notification.

*SPH/400
3-15-89
Attachment 2*

We are able to provide test results usually within 24 hours since the samples are included with our routine blood screening that is run almost daily. In cases where the sample is from an individual who is a potential organ donor, timely results are imperative.

I urge you to support HB #2327. This bill will not give blood banks any special consideration but would require blood banks to be reviewed and regulated as a laboratory by the secretary of health and environment in order to perform HIV testing that would qualify for reimbursement by third party payers. This is a highly utilized service which, if not partially provided by the blood banking community, could create inconveniences for physicians and individuals desiring testing.

To some of you, it might seem strange that blood banks are requesting an additional inspection. But I have no doubts that we would easily comply with the state requirements and that the inspection could be done at the same time the state inspects our facility for Medicare.

STATE OF KANSAS



DEPARTMENT OF HEALTH AND ENVIRONMENT

Forbes Field

Topeka, Kansas 66620-0001

Phone (913) 296-1500

Mike Hayden, Governor

Stanley C. Grant, Ph.D., Secretary

Gary K. Hulett, Ph.D., Under Secretary

Testimony Presented to
Senate Public Health and Welfare Committee

By

The Kansas Department of Health and Environment

House Bill 2327

Last year, KSA 65-1,107 was amended to require approval of laboratories performing serological tests for human immunodeficiency virus and tests for controlled substances in addition to the test for prenatal syphilis serology. Approval of laboratories performing prenatal syphilis serology tests is required under KSA 65-153f.

The expansion of approval of laboratories with regard to HIV testing and tests for controlled substances was sought because of their significance in public health and the resulting potential harm to an individual if inaccurate test results were obtained. The current approval process under Medicare, Kansas hospital licensure, and Clinical Laboratory Improvement Act of 1967 (CLIA) does not address these tests individually.

The approval process requires laboratories to meet certain personnel qualifications, utilize approved methodologies, develop an effective internal quality assurance program, and successfully perform on external proficiency audits.

External proficiency programs are one tool utilized to evaluate laboratories. The proficiency program sends unknown samples to the laboratory for analysis. Since these samples are identified to the laboratory as proficiency challenges, we recognize that such audits may reflect the capability of laboratory performance rather than day to day performance. Under the Medicare and CLIA approval process, there is no specific requirement for participation in proficiency programs for HIV or controlled substances.

SPH/W
3-15-89
Attachment 3

Drug screen tests are performed in a variety of settings, including the typical clinical laboratory, industry, private unregulated laboratories, and the criminal justice system. Drug testing technology is marketed as virtually 100% accurate with no training required to perform the test. A review of proficiency test results would suggest otherwise. In 1987, 21% of sample challenges were incorrectly reported; in 1988, 33% were incorrectly reported. These results were obtained from laboratories which do have ongoing quality assurance programs and staff with laboratory experience.

Regulation of laboratories performing HIV testing and tests for controlled substances is necessary to assure quality laboratory data. The Kansas Department of Health and Environment supports the blood banks and tissue banks who desire to be included in the approval process. Any exemptions to the requirements for approval seriously weaken the intent of the statute, which is to provide assurance of quality test results.

Presented by:

Theresa L. Hodges, M.A., M(ASCP)
Division of Laboratories and Research

March 15, 1989

Testimony on House Bill No. 2327
to
The Senate Public Health and Welfare Committee
by
Marla Williams, M.T., (ASCP), Supervisor
Immunochemistry Dept., Stormont-Vail Regional Medical Center Laboratory
March 15, 1989

The three tests covered under this bill--the syphilis and HIV serology, and the drug screen tests for abused substances--are performed in my department of the laboratory. For over eight years we have been performing drug screens. Our test volume has greatly increased in the past several years and includes not only tests for medical reasons, but also tests to monitor compliance with programs for behavior care units, Shawnee County Correctional facilities, and industry, among others. We have been offering HIV-antibody testing for about eighteen months. Therefore I am acutely aware of the social issues and technical problems associated with these tests.

I support the deletions as proposed in H.B. 2327. In fact, I strongly urge the removal of the entire exclusion clause (b). My fellow laboratorians and Dr. Hiszczynskyj, the Laboratory Director at Stormont-Vail, join me in recommending that there be no exception to the protection offered by this law.

Why was this bill signed into law last year? Was it not to assure the Kansas public that at least these three tests would be performed under certain minimal standard conditions and quality control checks? The medical, social, and economic impact of an inaccurate report can be devastating, as you know. These exceptions were added to the bill on the floor during the final vote, as I understand. Who is going to explain to the patient in a private physician's laboratory or to a parolee or inmate that they do not have the same right to a valid test result as someone else who unknowingly happened to utilize a laboratory that is approved by the state for such testing? We are talking about results which can take away a job opportunity, deny a teenager the trust of his parents, not to mention removal of certain freedoms, or results that can mean a death sentence.

Granted, following the state requirements will erode the profitability of testing for a facility not accustomed to accountability. But of all the laboratory tests available, surely at least these three tests, due to their extremely sensitive nature, should meet the mandated guidelines no matter where the testing occurs. I believe in this case we should not sacrifice quality for cost concerns. Why do the test at all if not willing to place your testing before the state evaluation process? Kansans receiving these tests deserve this consideration and expect it.

Thank you for this opportunity to express my suggestions and comments.

SPH4W
3-15-89
Attachment 4

THE ASSOCIATION FOR
REI ARDED CITIZENS OF KANSAS, INC.



1111 W. 59th TERRACE
SHAWNEE, KANSAS 66203 • (913) 268-8200

Hope through understanding

ROBERT ATKISSON
President
Stockton

MARIE LEACH
Vice President
Wichita

MARY DONDLINGER
Secretary
Hutchinson

ED REMPE
Treasurer
Hays

CAROL A. DUCKWORTH
Past President
Lawrence

March 15, 1989

BRENT GLAZIER
Executive Director

TO: Sen. Roy Ehrlich, Chairman
Members of the Senate Public Health and Welfare Committee

FROM: Lila Paslay, Chairperson
Legislative Affairs

RE: H.B. 2206

The members of the Association for Retarded Citizens of Kansas urges you to support H.B. 2206.

As we see many more individuals with mental retardation being served in community facilities, the possibility of abuse and/or neglect is increased. We also know that persons with more severe disabilities which includes behavior problems are at greater risk for such incidences. The protection provided in this bill would, hopefully, give assurance that cases of abuse and/or neglect would not go unreported and would insure improved care and safety.

We are concerned about the monitoring of this legislation. SRS will be transferring the monitoring of entities under K.S.A. 39-1401 to the Department of Health and Environment. Since the facilities in this bill are not medical as are those in K.S.A. 39-1401 we believe SRS would be the appropriate monitoring agency. We would like this issue to be addressed.

We ask you to support H.B. 2206 and vote it favorably out of this committee.

SPH/W
3-15-89
Attachment 5



Kansas Association of Rehabilitation Facilities

Jayhawk Tower • 700 Jackson • Suite 802
Topeka, Kansas 66603 • 913-235-5103

To: Senate Public Health and Welfare
Senator Roy Ehrlich, Chairman

From: Kansas Association of Rehabilitation Facilities

Re: HB 2206; reporting abuse or neglect of certain persons

Date: March 15, 1989

The Kansas Association of Rehabilitation Facilities is a state-wide Association representing not for profit community-based rehabilitation facilities. These facilities serve over 5000 (average daily attendance) children and adults across Kansas. The programs and services offered by these community programs include; vocational/employment; day activity; community living, children's services and support programs. The mission of these rehabilitation programs/services is for persons with a disability to gain maximum independence according to their abilities in a community setting.

The Kansas Association of Rehabilitation Facilities supports HB 2206 as amended by the House. The members of KARF have established policies regarding abuse and neglect. HB 2206 would make this a mandatory reporting process rather than an option. KARF supports this policy with regards to abuse and neglect.

KARF would request that legislative consideration be made regarding the statute designating the monitoring state agency. It is our understanding that SRS will be transferring the monitoring responsibility to the Department of Health and Environment for entities under K.S.A. 39-1401. This is appropriate for entities which are primarily medical providers. Community mental retardation facilities and residential facilities are primarily directed at rehabilitation/habilitation through a developmental model. It is important that the monitoring agency be familiar with such a service delivery model, historically that has been SRS.

KARF requests that the monitoring responsibilities be maintained with the Department of Social and Rehabilitation Services. That could be accomplished by changing the statute to be amended from K.S.A. 39-1401 to K.S.A. 39-1421. It is our understanding that K.S.A. 39-1421 speaks to community programs. Legislative Research or SRS could accurately detail these statutes. Another option is that through legislative intent SRS would be directed to maintain the monitoring of community programs as described in Section 1; Part 4 of this bill.

*SRA/4W
3-15-89
Attachment 6*

STATE OF KANSAS

GARY H. BLUMENTHAL
REPRESENTATIVE, TWENTY-THIRD DISTRICT
JOHNSON COUNTY
10125 EDELWEISS CIRCLE
MERRIAM, KANSAS 66203-4608
HOME (913) 262-4635
CAPITOL OFFICE (913) 296-7693



TOPEKA

HOUSE OF
REPRESENTATIVES

COMMITTEE ASSIGNMENTS
MEMBER: EDUCATION
LEGISLATIVE, JUDICIAL AND CONGRESSIONAL
APPORTIONMENT
TRANSPORTATION
JOINT COMMITTEE ON ADMINISTRATIVE RULES
AND REGULATIONS

Senate Public Health & Welfare Committee

3/15/89

Mr. Chairman, I appreciate the opportunity to share my remarks with the committee regarding HB 2206.

As many of you may know, I have spent many years working with advocacy groups concerned about the care and treatment of the mentally retarded. I introduced this bill as a result of my concern when I was contacted by an individual who worked in a facility for the mentally retarded, who had suspicions that a client in one of those facilities could possibly be the victim of abuse.

When this information was shared within the facility, there seemed to be a great amount of hesitation regarding whether this information should be shared with the area SRS office, in view of the fact that the mentally retarded person might not be fully able to articulate the allegation of abuse.

I feel quite strongly that in such a case when an allegation has been made, it should be the responsibility of the facility to immediately respond by notifying SRS and allow the appropriate individuals the opportunity to conduct an investigation and determine the validity of the allegation. Needless to say, I was quite surprised to learn that this is not necessarily the case or even standard procedure.

HB 2206 simply amends Kansas' abuse reporting statute, adding community mental retardation facilities (sheltered workshops) and residential facilities to the type of facilities that must report suspected cases of abuse. Reporting would be required only of appropriate licensed personnel within the facility. This procedure is identical to the procedures utilized for protection of residents within an adult care home.

At a time when many of our facilities for the mentally retarded are facing questions regarding appropriate care, protection from abuse, and active treatment, I feel we must extend this protection to ensure the quality of care within these facilities.

S. P. H. W.
3-15-89
Attachment 7