Approved 3-26-85
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 21, 1985 in room 526-S of the Capitol.

All members were present except:

Committee staff present:

Conferees appearing before the committee:
Azzie Young, Department of Health and Environment
Dr. Henry Travers, Wesley Medical Center, Wichita, Kansas
Kansas Society of Pathologists
John P. Smith, Kansas Society for Medical Technology
Representative Ben Foster
Dr. Courtney Clark, Wichita, Kansas

Others Attending: See attached list

Chairman Ehrlich called the meeting to order. He stated that he had adjourned the March 21, 1985, meeting with a motion by Senator Anderson and seconded by Senator Kerr to re-refer HB-2018 to the Federal and State Affairs Committee still on the floor. Senator Anderson had requested that he would like to withdraw the motion and there were no objections.

Emalene Correll presented a brief on HB-2076. This bill was offered to allow all medical facilities licensed by the Secretary of Health and Environment to operate a pharmacy if the facility is registered by the Board of Pharmacy.

Ms. Correll briefed the committee on HB-2078. This bill, requested by the Secretary of SRS would amend the statute as it defines terms utilized in social welfare. It would change the definition of "General Assistance" to authorize General Assistance to be limited to persons who are unable to engage in employment as defined in rules and regulations adopted by the Secretary of SRS.

Norman Furse briefed the committee on HB-2079. An opinion from the Attorney General ruled the statute was in violation of the provisions of the federal Social Security Act. This bill would amend the statute to delete the requirement that the Secretary of SRS maintain a public list containing names of recipients of Aid to Families with Dependent Children.

Norman Furse briefed the committee on HB-2082. This bill amends two statutes to increase the statutory maximums applicable to license fees, license renewal fees and fees for the reinstatement or copy of a license. It would require that examination fees be paid directly by applicants for licensure by examination directly to the examination services. Attachment I

Norman Furse briefed the committee on HB-2185. This bill would amend the statute dealing with screening tests for PKU, galactosemia, and hypothyrodism and require that the initial screening test be performed by the Department of Health and Environment for all infants born in the state.

Senator Francisco introduced his pages, Mikall Wayne Venso and David Allen Klassen from Newton, Kansas.

The Chairman welcomed students from Savior from the World Seminary and their instructor who were visiting the committee.

Azzie Young, Department of Health and Environment testified and presented written testimony supporting HB-2185. Attachment II The Department feels that

lack of centralized system to test, screen and track high risk infants, no uniform standard laboratory methods, no quality assurance and high costs were problems with the present system.

Representative Foster, author of HB-2076, introduced Dr. Courtney Clark from Wichita, who testified concerning the need for anesthesia to use in the operation of ambulatory surgical centers. It was stated that the doctors were obtaining drugs under their physician's license and the reports then are questioned by the Pharmacy Board.

Senator Walker made the motion to place HB-2076 on the consent calendar. The motion was seconded by Senator Francisco and the motion carried.

John P. Smith testified and presented written testimony opposing HB-2185. Mr. Smith stated that erroneous results due to clerical errors, degradation of the samples by heat, additional cost, quality control and delay in reporting test results were all important reasons to have the tests performed in the local area. Attachment III

Dr. Henry Travers testified and presented written testimony opposing HB-2185. Dr. Travers expressed concern with the quality of the tests due to transportation in hot weather, slow reporting on results, clerical errors, increase in total cost due to the fact that the sample still has to be drawn on location and liability. Attachment IV

Conferees opposing this bill were asked if they had testified in the House hearings and the report was that they were not aware of the bill at the time hearings were held.

Meeting adjourned.

SENATE

PUBLIC HEALTH AND WELFARE COMMITTEE

DATE 3,21,85

(PLEASE PRINT) NAME AND ADDRESS	ORGANIZATION
DICK HUMMEL TOPEKA	KHCA
Dr Lois R. Scibetta	KSB of Nursing
COURTNEY CLARK, M.D.	Surgicare of Wichita
Katharine Clark CRNA	KANA
Belva Ott	Registered Nurse Anesthetists
James F Orman	
Margaret Orman, R.N.	Surgicare of Wichita
DARLENE GREER STEARNS	Counsel + Members
Gary Robbins	KS Opt assn.
Jim McBride	United Way

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SUBCOMMITTEE REPORT

3760

Agency: Board of Nursing Bill No. 2036 Bill Sec. 14

Analyst: Howard Analysis Pg. No. 43 Budget Pg. No. 1-203

Expenditure Summary	Agency Req. FY 86	Governor's Rec. FY 86	Subcommittee Adjustments
State Operations:			
All Funds	$ 487,187	$ 390,604	$ —
State General Fund	—	—	—
F.T.E. Positions	11.0	11.0	—

House Subcommittee Recommendations

FY 1985. The Subcommittee concurs with the Governor's recommendation for FY 1985.

FY 1986. The Subcommittee concurs with the Governor's recommendation except for the following:

1. Reduce printing and advertising by $1,000 to $6,360, and shift that $1,000 to increase fees for other services from $7,000 to $8,000 to pay for data processing services and tuition fees.

In addition, the Subcommittee notes that the Executive Director has expressed dissatisfaction with the current salary ranges and the effect she feels that these have on attracting quality professional personnel. This Subcommittee has not had the necessary information to study this matter but we suggest that the Senate Subcommittee review this question if more information is available from the Division of Personnel Services.

Based upon the Subcommittee's recommendations, the balance remaining in the Board of Nursing Fee Fund will be $135,204 at the end of FY 1985 and $234,296 at the end of FY 1986. The fee fund analysis is shown below:

Resource Estimate	Actual FY 1984	Estimated FY 1985	Estimated FY 1986
Beginning Balance	$ 80,040	$ 90,889	$ 135,204
Net Receipts	415,386	438,802	489,696
Total Funds Available	$ 495,426	$ 529,691	$ 624,900
Less: Expenditures	404,537	394,487	390,604
Ending Balance	$ 90,889	$ 135,204	$ 234,296

House Committee Recommendation

The House Committee concurs with the recommendations of the Subcommittee.

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Attachment I

Senate Subcommittee Recommendations

Expenditure Summary	House Adjustments	Total House Recommend.	Senate Subcommittee Adjustments
State Operations:			
All Funds	$ —	$ 390,604	$ 4,836
State General Fund	—	—	—
F.T.E. Positions	—	11.0	—

The Senate Subcommittee concurs with the recommendation of the House with the following adjustments:

1. Add $432 to salaries and wages for the Executive Administrator. A change from Range 32 to Range 34 has been approved by Personnel pending some fund resources verification. The Subcommittee would note that the Executive Administrator had planned a move from 32-E to 34-F with a much larger salary increase. However, as a classified employee the Administrator is limited by Division of Personnel Regulation 1-5-19c from moving to Step F in the new range.

2. Add $4,404 in salaries and wages for a nursing education specialist which the Division of Personnel Services has approved hiring above the minimum step.

The fee fund analysis, based on the Senate Subcommittee's adjustments in FY 1986, is as follows:

Resource Estimate	Actual FY 1984	Estimated FY 1985	Estimated FY 1986
Beginning Balance	$ 80,040	$ 90,889	$ 135,204
Net Receipts	415,386	438,802	489,696
Total Funds Available	$ 495,426	$ 529,691	$ 624,900
Less: Expenditures	404,537	394,487	395,440
Ending Balance	$ 90,889	$ 135,204	$ 229,460

Senate Committee Recommendation

The Senate Committee concurs with the recommendation of the Subcommittee with the following adjustment:

1. The Committee notes the increasing ending balances and requests that the Board review their fee balances and implement lower rates if these balances are excessive.

KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

Testimony on HB 2185

Presented to the Senate Committee on Public Health and Welfare

This is the official position taken by the Kansas Department of Health and Environment on HB 2185.

Current Kansas statute, 65-180, requires that each newborn child be tested for phenylketonuria, hypothyroidism and galactosemia but does not stipulate how or where this should be done. These diseases result from inborn errors in metabolism which can lead to lifelong mental retardation in the absence of rapid detection and treatment. Prevention is accomplished through laboratory screening test, prompt follow-up and supportive therapy initiated within the first fourteen to thirty days of life. Time frames are short. The consequences of a missed case or a delay in treatment can result in permanent damage to the infant. Close association between the screening laboratory and the follow-up system is crucial.

The prevention of mental retardation is a significant public health issue. The Kansas Department of Health and Environment has operated a successful laboratory screening and follow-up program for many years. This program began with phenylketonuria in 1965. Screening for hypothyroidism was added in 1977 and galactosemia was instituted in 1985. Over thirty thousand Kansas newborn now receive screening tests and follow-up from the Department of Health and Environment each year. The remaining ten thousand infants are tested at one of eight private laboratories located across the state. While there may be some advantage to this diversified approach, the liabilities include the following:

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Attachment II

1. No centralized system to test, screen and track high risk infants.
2. No uniform standard laboratory methods.
3. No comprehensive quality assurance review or performance evaluation for these neonatal tests performed in local laboratories.
4. High costs associated with unnecessary diagnostic tests performed at some laboratories compared with low cost screening tests performed in a central high volume laboratory.

Most states have addressed these and similar concerns with a centralized program at the state or regional level. This approach is recommended by the American Academy of Pediatrics. These public health screening tests do not represent an intrusion upon the several million clinical diagnostic tests performed each year by the more than one hundred sixty certified Kansas hospital and independent laboratories.

Department's Position

The Kansas Department of Health and Environment supports this bill.

Presented by:

Barbara J. Sabol, Secretary
Kansas Department of Health
and Environment

3-21-85 - John Smith -

TESTIMONY PRESENTED

BY THE

KANSAS SOCIETY FOR MEDICAL TECHNOLOGY

BEFORE THE

SENATE COMMITTEE, PUBLIC HEALTH AND WELFARE

REGARDING

HOUSE BILL 2185

I, John P. Smith, a practicing medical technologist, am appearing before the Committee on behalf of the Kansas Society for Medical Technology. We appreciate the opportunity to provide the Committee with our position on House Bill 2185. The membership of the Kansas Society for Medical Technology is made up of over 300 clinical laboratory scientists, medical technologists and technicians who perform clinical laboratory tests in hospital, independent and physician office laboratories. H.B. 2185 mandates that initial laboratory screening tests for phenylketonuria, galactosemia and hypothyroidism be performed by the Department of Health and Environment for all infants born in the state. This restrictive wording would prevent laboratories that are currently performing these screening tests from continuing to offer these services. Although without examination, the centralizing of these tests appear to offer some advantage; there are many disadvantages. We oppose this bill for several reasons. These include:

. Erroneous results due to clerical errors:

With the testing laboratory located at a site remote from the infant, more people will be involved in handling, processing, identifying and reporting test results. This increases the possibility of sample misidentification, loss of sample, transcription and other handling errors.

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Attachment III

- Degradation of the Sample by heat:

The enzyme measured to test for galactosemia is destroyed by heat. Transportation of samples during hot summer months may result in degradation of the enzyme and false negative results.

- Additional cost:

House Bill 2185 states that "such services shall be performed without charge". Although the performance of the test by the state laboratory will be done without charge, the sending facility will charge for collection, shipment and record maintenance. If the test has to be recollected and repeated, these charges will probably be duplicated.

- Quality Control:

Although the rationale in support of central testing may be one of quality control, there are existing proficiency testing programs that can be used by the state and the local laboratory to monitor test performance. The state currently conducts a proficiency testing program for phenylketonuria (PKU), and the College of American Pathologists for hypothyroidism. Laboratories are now required to submit all proficiency test results to the Kansas State Department of Health and Environment. The state can monitor test performance for these tests through extension of the existing regulatory programs.

Delay in reporting test results:

Results of testing for galactosemia and hypothyroidism must be known by approximately 96 hours of age to prevent the development of irreversible liver and brain damage. Centralized testing may increase the time from collection and submission of the sample and reporting of the result beyond the 96 hour window. An added complication is that the blood sample should not be collected until 24 hours after initial feeding to insure accurate assessment of phenylalanine and galactose.

We prefer continuation of freedom of choice where laboratories can continue to perform these tests in the hospital where the birth occurred. Facilities who prefer to send the specimens to the Kansas State Department of Health and Environment's laboratory should have the option to do, but this should not be mandated. Voluntary proficiency testing programs for these screening tests exist. These programs allow the participants to compare their results with other laboratories and the Kansas State Department of Health to monitor test performance. This appears to us to be a more appropriate way to monitor quality and maintain cost effectiveness, rather than to simply mandate centralized testing by the Kansas State Department of Health and Environment's laboratory in Topeka.

In summary, the Kansas Society for Medical Technology can not support the implementation of centralized screening tests performed only by the Kansas State Department of Health and Environment laboratories. We support cost effective, accurate and timely screening testing for galactosemia, hypothyroidism and phenylketonuria. This can be more effectively through the present system with the requirement that laboratories who do these screening tests participate in a proficiency testing program.

John P. Smith
Kansas Society for Medical Technology
March 21, 1985

HB-2185-Dr. Travers — 3-21-85 —

TESTIMONY

BEFORE THE

SENATE COMMITTEE FOR PUBLIC HEALTH AND WELFARE

REGARDING

HOUSE BILL 2185

I am Dr. Henry Travers and represent both the Wesley Medical Center, Wichita, Kansas and the Kansas Society of Pathologists (KSP). Currently, I am the Associate Director of Laboratory Medicine at Wesley and the Vice President of the KSP.

House Bill 2185 provides for sending blood specimens for all newborns in the state to a central state-run laboratory in order to test for three diseases: phenylketonuria (PKU), galactosemia, and hypothyroidism. The State will not charge for these tests. This bill creates a number of difficulties which will adversely affect the care of infants in Kansas. In addition, there are cost, liability, and logistical considerations which are not obvious in the bill's simple rewording of the original legislation.

Quality Issues

A number of regional laboratories are currently providing testing for the three disorders mentioned previously in an expeditious and accurate manner. It is necessary that the results of these tests be known quickly, because irreversible damage to the brain and liver may occur after as little as four days following birth. Delays in shipping specimens to the state laboratory (a particular problem in the winter months), delays in test processing due to large test volumes, and delays in reporting results from the state laboratory can **unnecessarily postpone the delivery of vital health information.** This concern applies, of course, to the entire state, but in areas such as Wichita, where 25% of the state's babies are born, it is particularly important to avoid the sort of delays that would be anticipated with the passage of House Bill 2185.

The testing method for one of the three diseases concerning us here measures the activity of an enzyme. The enzyme measured to test for galactosemia is destroyed by heat. The transportation of specimens across Kansas during the typically hot summers may result in inactivation of this enzyme and the **reporting of falsely negative results.** While specimens can be transported using insulated containers, this method fails daily in the nations's laboratories for a variety of reasons. In the case of newborn screening, any failure of specimen delivery potentially threatens the life of an infant. Where heat has destroyed the enzyme, the laboratory must presume that the infant has galactosemia and institute not only confirmatory tests (an expensive proposition) but also a recommendation that the infant be treated for a time as if he had galactosemia.

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Attachment IV

Sending specimens to a central state laboratory increases the number of hands through which the specimens must pass and the number of clerical errors which are likely to occur. Beyond the issues of specimen integrity and test quality, **clerical errors** are a serious and recurring problem in all laboratories. This bill would increase the chances of such errors occurring. The misidentification of a baby as having hypothyroidism (which can lead to severe mental retardation) who, in fact, does not, is not nearly so devastating as identifying an infant as normal who, in fact, has hypothyroidism.

Large, well-run laboratories have been performing newborn screening for several years. Their quality has been monitored by the state. While I cannot speak for all laboratories, those with which I am familiar have met the state's requirements for quality. In fact, such laboratories in the past have been instrumental in pointing out factual errors in state-published material about certain tests (e.g. PKU screening) and have thus helped to fulfill their obligations to the health of the citizens of Kansas. With this kind of quality in the field, it is difficult to understand how centralizing testing facilities will positively influence the welfare of Kansas' newborns.

Operational Issues

The cost of this program to the Kansas taxpayer may be higher than estimated. The increased number of clerical errors that may be anticipated and problems with specimen transportation will require many tests to be repeated or to be confirmed using more costly test methods. While it is true that increasing test volume will lower the state's unit cost, the overall total cost is increased. The benefit to be derived from this increased expenditure is unclear. Already available in the state are hospital and private laboratories competently serving entire regions, providing newborn screening at competitive rates.

The tests will not be free even if performed totally by the Department of Health and Environment. Hospitals would bill for the cost of obtaining the specimen, handling it, transporting it to the state laboratory, and reporting the results. In some cases, these costs may exceed the state's cost for performing the test. In cases where repeat testing is necessary, these charges would be duplicated. With regard to repeat testing, some laboratories in the state do not charge for repeat testing when necessary, as long as the original testing is done in that laboratory. Thus, handling costs alone will dramatically **increase the total cost** of newborn screening in Kansas.

The question of **liability** is complicated by the proposed need to transport specimens to a central laboratory. Who is responsible for delays in delivery? for damage to the specimens? for clerical errors in reporting? Physicians and hospitals have become acutely sensitive to liability issues in the recent past, and questions dealing with specimen integrity and result reporting are central to a laboratory's interests. To send specimens to a central laboratory when there is nothing to be gained therefrom creates needless liability issues and increases the cost of health care.

Summary

Some hospitals and laboratories in Kansas have, for some years now, competently and efficiently conducted screening of newborn infants for phenylketonuria (PKU). More recently, screening for hypothyroidism has been carried out, and currently galactosemia screening has been added. Infants are tested promptly, carefully, and at nominal cost. Results are reported quickly and follow-up studies are carried out in a coordinated manner. Physicians can quickly and easily discuss the testing and obtain consultation from laboratory physicians at local sites. Quality has been consistent with that required by the state. Passage of House Bill 2185 will result in higher screening costs, increased risks for newborn infants (from clerical errors, specimen handling errors, and specimen damage), and increased liability for hospitals, laboratories, and the personnel who run them. While we support cost-effective, accurate, high-quality, and timely testing to reduce the potential of mental redardation within the state, a goal no different from that of the Department of Health and Environment, we do not see any clear public good which would offset the above problems that House Bill 2185 would engender.