Committee in Session at 8:30 A.M. on Tuesday, March 6, 1979.

Senator Keith Ashworth in the Chair.

PRESENT: Chairman Keith Ashworth
Senator Clifton Young
Senator Rick Blakemore
Senator Wilbur Faiss
Senator Jim Kosinski

ABSENT: Vice-Chairman Joe Neal.

GUESTS: Assemblyman John M. Vergiels, District 10.
Henry Soloway, Associate Pathologist, Las Vegas.
David Cocanower, Blood System
Peter V. Van Schoonhoven, M.D., Vice President and Medical Director for Blood Systems, Inc., Scottsdale, Arizona.
Mr. Maynard Yasmer, Rehabilitation Division.
Carroll L. Spurling, Director of Los Angeles, California Red Cross Blood Services.
Dr. Salvadorini, retired Laboratory Director, Washoe Coun
Assemblyman Paul Prengaman, District 26.

Chairman Ashworth opened the hearing on A.B. 149.

Assemblyman Vergiels spoke in support of A.B. 149. He stated it is an invasion of privacy. The blood donors are not aware that information as to adverse conditions in their blood is sent to a central depository in Arizona. Dr. Vergiels is opposed to this information being brought back to be used against the donor. A.B. 149 provides for manual recording rather than by computer. Dr. Vergiels is against central location of any files. He stated that Blood Services checks for quality to make sure that the blood does not have any kind of disease. He stated that donors are notified if this is the case.

Henry Soloway, Associate Pathologist, Las Vegas stated that A.B. 149 is basically whether medical confidentiality extends to doctor/patient relationships. They exist in the modified way in the blood bank. The medical records are confidential. The patient signs an authorization to release this information. In blood banking the confidentiality of records does not exist. On a regular basis a listing of permanently disqualified blood donors is sent to the various blood banks, blood services systems, indicating the donor and the reason for disqualification. The Red Cross similarly transmits lists of donors with hepititis. In Nevada, the donor's permission isn't asked for. The consumers, National Leukemia Foundation, Hemophilia Foundation, American Cancer Society, Heart Society are quite well organized and have cash flow. They have lobbyists and administrators who look out for the welfare of the persons they represent. Practically all the whole blood is altruistically donated.

Senator Ashworth questioned if this bill deals only with those who donate their blood, and if it did not cover the person who sells their blood.

Dr. Soloway stated that the person who gets paid for the donation of their blood gets paid to take the risk. Blood is taken by assistants who work under the direction of a licensed physician.

Senator Kosinski stated that this committee has heard at least two bills relating to confidentiality of patient's records, and has wisely recognized the public policy interest in maintaining confidentiality of patient's records.There are policies which require a different perspective or a compromise of some sort. The Federal Government has developed an approach to reviewing the quality and quantity of provider's services. In developing the approach they have come up with some stringent, and probably necessary guidelines in restricting the dissemination of information. It is necessary to recognize there are different public policies on these issues that have to be reconciled.

Dr. Soloway stated that the P.S.R.O. (Professional Standards Review Organization) has been in effect for a good many years and that the Federal Government does have a strong interest in protecting confidentiality. The point of this bill is to protect the donor; the dangers of hepititis was explained. Public Health measures are provided to advise people of any adverse condition of their blood and to advise them not to give blood again. Cost of blood represents 2% of medical care.

David Cocanower, Associate General Counsel of the Blood System spoke against the A.B. 149. He spoke of the legal aspects and contractual regulations presently existing between Nevada Blood Banks and the Veteran's Administration. He stated he would make copies of these Federal Regulations and report back. He made the point that it is crucial the purity of blood be insured and be traceable to its origin and be identifiable with very careful record keeping. The blood is traced through the social security number not the donor's name. It is only accessible to the location where the donor gave the blood and the Bureau of Biologics, (the agency charged with regulating blood banks), and is a National System. Blood Systems, Inc. of Arizona is a non-profit corporation that operates with 19 blood centers, other than the northern area of Nevada that is served through the Red Cross.

Senator Ashworth announced, for the record, that Mr. Cocanower had presented pieces of correspondence (Exhibit "A"), which were the blood bank testimony before the Assembly Committee.

Peter Van Schoonhoven, M.D., United Blood Services, Scottsdale, Arizona, Medical Director of Blood Systems, Inc. stated what happens to a blood donor and the record system in a blood center. (Exhibit "B").
To satisfy U.S. licensure requirements, as explained in Section 606,

it is necessary to maintain a record of all temporarily, or disqualified donors. This record is retained in the Center for 5 years by law, and then destroyed. Blood can be maintained for 21 days in the liquid form before use. The disqualified donor directory is not shared with any other State. This directory is sent to all the blood centers in Nevada but nowhere else.Compatibility testing is done at the time it is given to the receiver. Blood can be frozen to keep for a longer period than the 21 days. The expiration date of frozen blood is 3 years, but some units have been used up to 7 years with no adverse affect. Blood is also sold in various other forms. Last fiscal year, Reno drew 11,300 donor units; in Las Vegas 21,400. The state used about 26,000 units from that fiscal year.

Carroll L. Spurling, Director of the Los Angeles Orange County Red Cross Blood Services and representing the National Red Cross Organization Blood Organizations of Blood Services, spoke to support the position against A.B. 149 taken by the two previous speakers. He stated that we are required, by law, to provide positive identification of the donor and the blood unit and be able to trace every event of that blood unit. Safeguarding the donot is of prime concern relating to confidentiality.

Senator Kosinski questioned whether the Red Cross would stop operating in the State of Nevada if this bill was not passed.

Mr. Spurling stated it would provide some real obstacles and would force them to perform their activities in what they would consider a less than optimal way.

Dr. Salvadorini - now partially retired, was Clinical Director and Laboratory Director in the Washoe Center for 27 years and for 18 years Medical Director of Blood Services in Reno. The Medical Society started a blood bank in Reno which is now a beautiful service with good interchange. He feels the bill is a good one and asks for consideration of this bill.

The hearing on A.B. 149 was closed as there was no further testimony.

Senator Ashworth opened the hearing on A.B. 253.

Assemblyman Paul Prengaman, District 26, spoke in support of A.B. 253. He stated the bill is basically to permit operation of small canteens in residential programs for the mentally retarded - the Sierra Developmental Center and the Desert Developmental Center. At the time of development of these centers there was space provided for these canteens. No fiscal impact would be involved or state monies involved. If there happens to be any profit, it will be used in the recreational facility for their programs.

Senator Ashworth posed the question of what would be done about profit or loss.

Assemblyman Pregaman stated use of a vending machine would be a good beginning. According to existing law notification must be given to the Bureau of Services of the Blind who then undertake a survey as to suitablility. This survey is then submitted to the agency.

Chairman Ashworth questioned conflict or competition with the Bureau of Services to the Blind.

Assemblyman Pregaman stated the Bureau of Services to the Blind has priority rights to operate these canteens, but not the exclusive right. This bill is restricted to the state mentally retarded, and was an agency request.

Mr. Maynard Yasmer, Rehabilitation Division stated there is the feeling of conflict as to the operation of vending standards on government property. Mr. Yasmer stated that to obtain appropriations for a canteen, they could contact the commercial people or obtain a contingency fund from the agency; thereby establishing some kind of reasonable operation.

Chairman Ashworth suggested the Division of the Blind and Mr. Middleton work out conflicts without eroding, and perhaps come up with an amendment.

Mr. Yasmer stated that he believes A.B. 253 is unnecessary.

Chairman Ashworth expressed confusion with the bill. He questioned abuse of the system to the mentally retarded, overstepping the blind program, origination of funds and who benefits.

There being no further testimony, Chairman Ashworth closed the hearing on A.B. 253.

Chairman Ashworth reminded the committee the hearing for Wednesday, March 7, 1979 would start at 9:00 A.M.

There being no further business, Chairman Ashworth adjourned the meeting at 10:50 A. M.

Respectfully submitted,

Jean Van Nuys
Committee Secretary

Approved:

Chairman
Senator Keith Ashworth

10|156205 (EXHIBIT A)

		Preparation MO DAY YR HR A-P BY	WRBC, FRBC OR 24-HR RBC	Expiration HR A-P	LABLE
WB		CELL SEPARATION			
21-DAY RBC					
WRBC		PLATELET SEPARATION OR CAHF FREEZE	PLTS		
FRBC					
24-HR RBC		FSDP FREEZE OR CAHF RE-FREEZE	CAHF		
EXP		WRBC	FSDP		
		SALINE SET MFR LOT No.	RPRT		
			RPF		
			R P DSTRY		

Special Technics
- ☐ 21-day RBC separated by sedimentation
- ☐ Red unit prepared from RBC or WB as indicate
- ☐ Other: See comments, 4. Processing

TEST	AGG OR HEM POS	NEG	TYPE
ANTI-A			
ANTI-B			

REPEAT	AGG OR HEM POS	NEG	TYPE
ANTI-A			
ANTI-B			

DATE MO DAY YR

4. PROCESSING

COMMENTS

DATE MO DAY YR

TEST BY	AGG OR HEM POS	NEG	TYPE
A-CELL			
B CELL			
ANTI-D			Rh
REPEAT D			
D^u			
D-AGT			
ABDY SCRN SAL			
AGT			
ABDY CODE			
STS			
HBsAg			
BY			

REPEAT BY	AGG OR HEM POS	NEG	TYPE
A CELL			
B CELL			
ANTI-D			Rh
REPEAT D			
D^u			
D-AGT			
ABDY SCRN SAL			
AGT			
ABDY CODE			
STS			
HBsAg			
BY			

EXPIRES MO DAY YR | ABO | D/D^u | BUI No.

1. REGISTER

DONATION DATE MO DAY YR | ABO | D/D^u | BUI No.

BUI No. 10 156205

LABELED BY

LAST NAME FIRST MIDDLE

M F

STREET

CITY STATE ZIP

S S No.	BIRTH DATE	No. DON	LOC	ORG	INS	TIMES/YR

HOME PHONE BUSINESS PHONE EXT P I T DEFER

DONATING FOR

I collected the required amount of this donor's blood into a non-defective ☐ single ☐ double ☐ triple ☐ quad blood bag at _____ AM _____ PM from the ☐ left ☐ right arm for CPD ____ whole blood. Phl. _____

AMERICAN RED CROSS BLOOD SERVICES BS 300 (Rev. 5/78)

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BUI No.

10

EXHIBIT A

Expiration

WB	
21-DAY RBC	
WRBC	
FRBC	

PLTS	
CAHF	
FSDP	
RPRT	
RPF	

TEST	POS	NEG
ANTI-A		
ANTI-B		

REPEAT	POS	NEG
ANTI-A		
ANTI-B		

	POS	NEG
A-CELL		
B CELL		
ANTI-D		
REPEAT D		
D^u		
D-AGT		
ABDY SCRN SAL		
AGT		
ABDY CODE		
STS		
HBsAg		

	POS	NEG
A CELL		
B CELL		
ANTI-D		
REPEAT D		
D^u		
D-AGT		
ABDY SCRN SAL		
AGT		
ABDY CODE		
STS		
HBsAg		

EXPIRES MO DAY YR

ABO | D/D^u

REGISTER

DONATION DATE MO DAY YR

BUI No.

10[illegible]20[illegible]

ABO D/D^u

LABELED BY

BLOOD SERVICES

267

BLOOD BANK TESTIMONY
ON
ASSEMBLY BILL 149

This Bill directly contravenes the Code of Federal Regulations relating to blood banking.

It would impair the obligations placed upon blood banks by existing contracts.

It would substantially increase the cost of blood distributed in Nevada.

The health needs of Nevada are served by two of the nation's more efficient blood banking systems, Blood Services and the American Red Cross. These organizations coordinate services to Nevada through centralized computer monitoring in Phoenix, Arizona and Salt Lake City, Utah, respectively.

Both facilities are licensed and strictly supervised by the Bureau of Biologics of the Federal Drug Administration which mandates the donor records that must be kept and the reporting which must be made.

1. <u>The Cost Factor</u>:

If this Bill should become law the cost of supplying blood services to Nevada would increase substantially, because it would require a second computer system for Nevada. This increase could vary from 10 percent to 25 percent. Even then the added computer system would not alleviate the dilemma to the blood banks of either complying with this law or violating the Federal Regulations imposed upon all federally licensed blood banks.

2. <u>The Veterans Hospital Problem</u>:

Blood Services would be required by this Bill to violate its existing contract with the Veterans Administration. For this reason, the Bill would be unconstitutional. The contract provision in existence, which is required by the Veterans Administration in the supply of blood to all Veterans Hospitals including the one in Reno, is as follows:

> "Donor Requirements:
> A. Blood Banks <u>must</u> maintain readily available lists of names, addresses, and social security numbers of all donors. Such list should indicate whether and on what date blood of a particular donor is furnished to the Veterans Administration under this contract." (The underlining is in the contract)

3. Federal Regulation Problem:

Regulation 606.160 C.F.R. (Exhibit A) designates what the donor records shall be. A licensed blood bank must abide by these regulations of the Bureau of Biologics. Even if a substitute number were ascribed for the donor, in lieu of social security number, for the separate Nevada computer, there would still be a violation of this Federal Regulation. The proposed law prohibits dissemination concerning a donor outside the Blood Bank where the donation is made, unless the donor signs an authorization for this purpose. One should note Regulation 606.165, which is also a part of Exhibit A, relating to distribution records which shall be made available to and in some instances reported to the Bureau of Biologics.

4. The Vagueness Problem:

The Bill proposes a statute which would be vague, indefinite and truly difficult of enforcement. The term "Blood Bank" is not defined and yet dissemination out of that location is prohibited. If the blood is drawn in a mobile unit in Carson City, can the donor records be delivered to the Blood Center in Reno? In other words, does this term apply to the place where the blood is drawn, the place where the blood is processed, the place where the records are kept, or the place where the blood is delivered to the hospital? In other words, does it include the hospital blood bank?

The proposal is also vague as to the term "adverse consequences." We are not aware of any adverse consequences resulting from the dissemination in a confidential fashion within blood bank records and within Bureau of Biologics standards for the dissemination of the requisite information in order to promote compliance. The nature of these adverse consequences should be set forth before. Otherwise, the blood bank has no way to know what it should advise the person executing an authorization.

5. The Confidentiality Factor:

Blood Services takes every care in enforcing privacy and confidentiality as to its records. We submit as Exhibits to this, pages 3-201 and 3-403 of the Blood Services Operating Manual which is binding upon every employee connected with the collection and distribution of donated blood. Laxity in these precautions and admonitions is not permitted.

EXHIBIT B

FDA

Subpart I—Records and Reports

§ 606.160 Records.

(a) (1) Records shall be maintained concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced. All records shall be legible and indelible, and shall identify the person performing the work, include dates of the various entries, show test results as well as the interpretation of the results, show the expiration date assigned to specific products, and be as detailed as necessary to provide a complete history of the work performed.

(2) Appropriate records shall be available from which to determine lot numbers of supplies and reagents used for specific lots or units of the final product.

(b) Records shall be maintained that include, but are not limited to, the following when applicable:

(1) Donor records:

(i) Donor selection, including medical interview and examination and where applicable, informed consent.

(ii) Permanent and temporary deferrals for health reasons including reason(s) for deferral.

(iii) Donor adverse reaction complaints and reports, including results of all investigations and followup.

(iv) Therapeutic bleedings, including signed requests from attending physicians, the donor's disease and disposition of units.

(v) Immunization, including informed consent, identification of the antigen, dosage and route of administration.

(vi) Blood collection, including identification of the phlebotomist.

(2) Processing records:

(i) Blood processing, including results and interpretation of all tests and retests.

(ii) Component preparation, including all relevant dates and times.

(iii) Separation and pooling of recovered plasma.

(iv) Centrifugation and pooling of source plasma.

(v) Labeling, including initials of person(s) responsible.

(3) Storage and distribution records:

(i) Distribution and disposition, as appropriate, of blood and blood products.

(ii) Visual inspection of whole blood and red blood cells during storage and immediately before distribution.

(iii) Storage temperature, including initialed temperature recorder charts.

(iv) Reissue, including records of proper temperature maintenance.

(v) Emergency release of blood, including signature of requesting physician obtained before or after release.

(4) Compatibility test records:

(i) Results of all compatibility tests, including crossmatching, testing of patient samples, antibody screening and identification.

(ii) Results of confirmatory testing.

(5) Quality control records:

(i) Calibration and standardization of equipment.

(ii) Performance checks of equipment and reagents.

(iii) Periodic check on sterile technique.

(iv) Periodic tests of capacity of shipping containers to maintain proper temperature in transit.

(v) Proficiency test results.

(6) Transfusion reaction reports and complaints, including records of investigations and followup.

(7) General records:

(i) Sterilization of supplies and reagents prepared within the facility, including date, time interval, temperature and mode.

(ii) Responsible personnel.

(iii) Errors and accidents.

(iv) Maintenance records for equipment and general physical plant.

(v) Supplies and reagents, including name of manufacturer or supplier, lot numbers, expiration date and date of receipt.

(vi) Disposition of rejected supplies and reagents used in the collection, processing and compatibility testing of blood and blood components.

(c) A donor number shall be assigned to each accepted donor, which relates the unit of blood collected to that donor, to his medical record, to any component or blood product from that donor's unit of blood, and to all records describing the history and ultimate disposition of these products.

(d) Records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions. The retention period shall be no less than 5 years after the records of processing have been completed or 6 months after the latest expiration date for the individual product, whichever is a later date. When there is no expiration date, records shall be retained indefinitely.

(e) A record shall be available from which unsuitable donors may be identified so that products from such individuals will not be distributed.

§ 606.165 Distribution and receipt; procedures and records.

(a) Distribution and receipt procedures shall include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall, if necessary.

(b) Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number of the unit(s), the date of expiration or the date of collection, whichever is applicable, or for crossmatched blood and blood components, the name of the recipient.

(c) Receipt records shall contain the name and address of the collecting facility, date received, donor or lot number assigned by the collecting facility and the date of expiration or the date of collection, whichever is applicable.

§ 606.170 Adverse reaction file.

(a) Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product arising as a result of blood collection or transfusion. A thorough investigation of each reported adverse reaction shall be made. A written report of the investigation of adverse reactions, including conclusions and followup, shall be prepared and maintained as part of the record for that lot or unit of final product by the collecting or transfusing facility. When it is determined that the product was at fault in causing a transfusion reaction, copies of all such written reports shall be forwarded to and maintained by the manufacturer or collecting facility.

(b) When a complication of blood collection or transfusion is confirmed to be fatal, the Director, Bureau of Biologics, shall be notified by telephone or telegraph as soon as possible; a written report of the investigation shall be submitted to the Director, Bureau of Biologics, within 7 days after the fatality by the collecting facility in the event of a donor reaction, or by the facility that performed the compatibility tests in the event of a transfusion reaction.

606.160 (b)(1)(ii)

EXHIBIT B

Donor Selection

3-201 GENERAL

Donors are accepted only if they meet specific established standards. The conduct of the interview and documentation of replies and observations are as stated in this Sec. 200. Positive identification of the donor at the time of registration, during the screening procedure, and through the collection of blood identifies records with the unit of blood. All procedures remain the same whether the interview is conducted in a main center, drawing center or mobile unit.

There are two prime considerations in selecting donors -- protection of the donor against any ill effects of the donation and protection of the prospective recipient against any transmissible disease or ill effects from the transfusion.

.01 INFORMED DONOR CONSENT - As the donors present themselves, each donor is given the pamphlet For Your Information and Benefit, BS 351, to read. It informs the donor of the procedure of donating blood.

.02 PERSONNEL - The donor registration is prepared by adequately trained persons who understand the need for accuracy and strictly adhere to procedures. The donor interview is conducted only by persons specifically trained for this position and for whom a Staff Qualifications - Interviewing Donors, BS 384, is in file, Sec. 105.

.03 DONOR PRIVACY - Donor medical history and screening information is confidential. Essential, accurate personal information is obtainable only in an atmosphere of privacy. The interview is, therefore, conducted in an area where questions and replies can not be overheard by other donors.

.04 CONDUCT - A professional but friendly attitude is maintained in a manner that will allay donor apprehension. Questions are asked slowly and distinctly to be sure the donor hears, understands and gives a straightforward reply. Adequate time is allowed for discussion and explanation. Show your interest in each donor and the importance of obtaining a good history by careful, thorough questioning. Never allow the interview to become a rapid, routinized, toneless series of questions.

.05 DEFERMENT - Nonacceptable replies to donor interview questions defer or disqualify the donor permanently (P) or temporarily (T). In the Defer Box, Section 1 Register, enter X under P or T, followed by the two digits representing the question number. This is referred to as the defer code. To enter a permanent deferment due to a nonacceptable reply to question number 04, enter code P04 in the Defer Box (X under P; 04 to the right, under Defer). Use P only as indicated in Sec. 203, as these are entered in the DDD and the donor may not be drawn while the name appears.

EXHIBIT B.

3-403 DISQUALIFIED DONOR DIRECTORY (DDD)

Each donor with a history of viral hepatitis, a reactive Hepatitis B surface Antigen (HBsAg) test, or involved in a reported case of TAH is automatically processed through Electronic Data Processing (EDP) in the Central Office. On the basis of the donor interview and processing results, donors disqualified for medical reasons and those with reactive STS and, in some cases, those with antibodies are likewise processed through EDP. A reinstated or retained donor's name will have been removed from the disqualified listing. The DDD is published monthly and the date is indicated on each page.

.01 FORMAT - The disqualified listing of donors is by facility, alphabetical, and includes donor's name (last, first and middle), sex, donor number (Social Security No.), birth date, date disqualified, and disqualification code. The disqualification code description is listed. The Central Office listing includes the Case Number of suspected TAH donors.

.02 CODES - The following codes are used in the DDD:

04 History Major Medical
05 History Hepatitis
08 Medications
10 Malaria
13 Chronic Asthma
14 Drug Addiction
15 Convulsions, Fainting
21 Chronic Skin Disease
26 Unsuitable Donor
32 Not Cleared Hep Case
33 Pos Hepatitis Test
34 Pos RPR Test
35 Pos Antibody Test

.03 INFORMATION PRIVACY - The contents of the DDD are considered to be privileged information. Only United Blood Services personnel have access to the information. Inquiries from others are referred to the Central Office.