

NORTH CAROLINA GENERAL ASSEMBLY

LEGISLATIVE FISCAL NOTE

BILL NUMBER: House Bill 1256 (3rd Edition)

SHORT TITLE: Voluntary DNA Database

SPONSOR(S): Representatives Miller and Walend

		FISCAL IMPACT				
		Yes (X)	No ()	No Estimate Available ()		
		<u>FY 2003-04</u>	<u>FY 2004-05</u>	<u>FY 2005-06</u>	<u>FY 2006-07</u>	<u>FY 2007-08</u>
REVENUES:						
DHHS	See assumptions and methodology; Dependent on number of participating firms: first year each firm pays \$25,000 and subsequent years the fee is based on actual costs.					
EXPENDITURES:						
DHHS						
Recurring	\$207,358	\$276,477	\$276,477	\$276,477	\$276,477	
Non-recurring	\$65,000	<i>(Additional costs for lab and equipment not included. Estimates not available for these additional costs.)</i>				
Additional Costs per DNA Sample						
Collection Kit (<i>per kit</i>)	\$5	\$5	\$5	\$5	\$5	
Analysis and Testing Contract (<i>per sample</i>)	\$200-\$300	\$200-\$300	\$200-\$300	\$200-\$300	\$200-\$300	
Correction	Exact amount cannot be determined					
Judicial	Exact amount cannot be determined					
ADDITIONAL PRISON BEDS*	No significant impact anticipated					
POSITIONS: (cumulative)		The analysis identifies the creation of three receipt-supported positions . Total positions will be determined by the level of outsourcing of program activities.				
PRINCIPAL DEPARTMENT(S) & PROGRAM(S) AFFECTED:		Department of Health and Human Services; Department of Correction; Judicial Branch				
EFFECTIVE DATE:		October 1, 2003				
*The intent of this legislation is that no General Fund monies be expended on this program.						

BILL SUMMARY: The proposed legislation adds new Part 34 to Article 3 of GS Ch. 143B to create a databank of DNA and related medical records in the Department of Health and Human Services (DHHS) for scientific research and study. The DNA databank will house voluntary submissions by individuals of DNA samples linked with each individual's medical record. The legislation states that the principal purpose of the DNA database is to advance scientific study of links between genetics and common diseases to improve diagnosis and treatment of these diseases. It contains provisions on the DHHS's responsibilities regarding collection of samples, access to database information, confidentiality of records, and segregation of records. It establishes a Class 1 misdemeanor offense for knowing, unauthorized disclosure of DNA information. Fees that DHHS may charge for providing data to corporations and research institutions are set. Departmental receipts stemming from the authorized fees, grants, gifts, and donations are the only funds available creating and operating the proposed DNA database. It is the intent of this bill that no funds, other than those obligated in this act, be expended for the creation and operation of this database. **No general fund dollars are obligated in this act.** The act becomes effective October 1, 2003.

ASSUMPTIONS AND METHODOLOGY:

Department of Health and Human Services

Revenues

The proposed legislation allows DHHS to collect reasonable fees equal to the cost of storing and retrieving information from the DNA database. North Carolina-based biotechnology corporations and research institutions participating in the database program will pay a fee of twenty-five thousand dollars (\$25,000) for the first year of operating the database. Revenues associated with the DNA database will depend on the number of biotechnology corporations and research institutions choosing to participate. Fees in subsequent years will be based on the actual cost of maintaining the DNA database, as determined by DHHS. The bill allows for DHHS to collect grants, gifts, and other one-time donations for the purpose of operating the DNA database. These departmental receipts are the only funds available for the purpose of creating and managing the DNA database. **Interest in the DNA database by biotechnology corporations and research institutions is unclear at this time. Without participation estimates, no revenue projections can be determined. This analysis includes no revenue projections.**

Expenditures

The total cost of establishing and maintaining a DNA database includes the cost of collecting and processing the DNA samples and medical records, storing the DNA samples, purchasing and maintaining the supplies and computer equipment necessary for the DNA database, and performing analysis and testing on the DNA samples. The proposed legislation allows DHHS to contract out for portions of the handling and testing of DNA samples, whether with a state university or with a biotechnology/research organization.

The database implementation could be structured with three tiers of activities: 1) collection, storage and stain card transfer of DNA samples; 2) electronic transfer and testing of medical records and DNA samples; and 3) actual research and usage of the DNA database. Funding levels could dictate the speed at which the DHHS DNA database effort progresses from one tier to another.

Based on information provided by DHHS, this analysis assumes that DHHS retains ownership and maintenance of the DNA database and performs most activities in-house. DHHS would incur costs for laboratory space and equipment, storage, computer equipment, and personnel. Based on information provided by DHHS, this analysis assumes that DHHS would hire a Medical Laboratory Technologist, a Computing Consultant V, and an Office Assistant IV at a total recurring cost of \$186,477.

Marketing and promotion - It can be assumed that various media channels would pursue the DNA database because it is a new and emerging idea. However, DHHS would still require some funding for advertising to obtain volunteers for the database and promotion of the database for economic development purposes. **This fiscal note assumes an annual expenditure of \$50,000 for promotion and advertising.**

Collection process - DHHS is granted the authority to adopt rules establishing the procedures for the collection of DNA samples from voluntary participants. Many alternatives exist for collecting and handling the DNA samples. Individuals could volunteer to participate and be shipped individual collection kits or DHHS could establish collection sites across the State. This fiscal note assumes a single collection point where DHHS would establish an intake process for medical records and DNA samples, and volunteers would receive a collection kit through the mail, provide a DNA sample, and return the kit to DHHS.

A detailed medical interview/questionnaire must also be conducted. If individuals are able to submit personal medical records with DNA samples, a detailed questionnaire and submission procedures must be established, taking into consideration individual privacy issues. The bill directs that specific representatives of genomics institutions participate in the formulation of the detailed medical questionnaire. Depending on the implementation details, volunteers could request paper questionnaires or submit electronic questionnaires via the Internet; volunteers may need to work with their physicians to fill out the detailed medical history.

Paper questionnaire - The paper questionnaire would then be returned to DHHS for inclusion in the DNA database and input into the electronic database using a standard data entry FTE calculation. Each sample would require 20 to 30 minutes to enter electronically, depending on the level of information contained in the questionnaire. The method of delivery for the questionnaire to potential volunteers is unknown at this time. Potential printing and postage costs for the questionnaire were not developed for this analysis.

Electronic questionnaire - Another alternative is an online medical interview, which would allow for automated electronic data capturing. Initial estimates for software range between \$5,000 and \$15,000 with annual maintenance costs around \$2,000. The Information Systems Division (ISD) in the General Assembly estimates that to write a custom application for this effort would involve a system analyst, programmer and database designer with average salaries of roughly \$50 per hour. Design and implementation of such a project is estimated to take approximately six weeks. Thus, a six-week project with an average salary of \$1,200 per week per employee (three employees) would present a total project cost of \$21,600. Depending on the involvement of the staff this cost could be

between \$15,000 and \$30,000. **This fiscal note assumes the software and design of an online process for medical interviewing and data collection will cost approximately \$30,000.**

Collection kits - Various DNA collection methods may be used, such as blood, cheek swab or hair root samples, each with varying costs. Blood samples are the only samples that require stain card transfers, which could be performed in-house or outsourced (see options below.) Blood samples are also the most reliable method to collect DNA and – once transferred to dry stain cards – are the most enduring sample that can be taken. Costs to other state agencies for DNA collection kits range from \$2 to \$4.50 per kit based on method and volume, and it is assumed that collection kit costs for DHHS will be similar. Postage to mail the kits to/from individuals back to the State for tracking is \$0.50 each. **This fiscal note assumes a kit collection cost of \$5 per sample.**

Blood sample storage - A special laboratory freezer is required to store the DNA samples once collected, and the cost for a freezer that holds 10,000 samples is approximately \$10,000. The price is dependent on the size, temperature limits, alarm systems, and recording devices selected. **It is assumed that DHHS would only require one freezer for \$10,000 during the initial stages of the database implementation.**

Lab space and a lab technician would be required to transfer DNA *blood* samples to stain cards to preserve them prior to medical testing. DHHS must hire staff/secure space *or* contract with another organization to perform these activities. (If medical testing were to occur immediately DNA samples were not preserved for further research, the stain card transfer step would not be necessary.) The DNA transfer would require a sterile environment for lab space that includes proper countertops and biological hoods to protect from airborne pathogens. It has been recommended that lab technicians who will perform the stain card transfers have at least a two-year degree in a biological science to understand the safety and procedural issues associated with this process. **It is assumed that staffing for stain card transfers would require approximately \$40,000 annually; however, equipment costs and lab space are unknown and are not calculated in this figure.**

DNA database - A computer database would be necessary to house the DNA sample data as well as electronic medical records for participating individuals. Information submitted on paper questionnaires must be converted to electronic form and entered into the database. DHHS must hire staff *or* contract with another organization to perform this conversion/data entry. The computer system is estimated to store approximately 20,000 electronic medical records along with the relevant DNA data; however, the estimate is based on the size of DNA samples in the State Bureau of Investigation DNA database. The information stored in the DHHS database will be different records of DNA strands that have coding for genetic traits, thus the sizing may be different. **This analysis assumes that operating the DNA database will cost \$89,265 in personnel. The start-up costs for the DNA database itself are assumed to be \$25,000, developed from information supplied by ISD and DHHS. If an online medical history submission database were to be created (see above), the total computer equipment cost for the database minus would be approximately \$119,265 (\$30,000 + \$89,265).**

To perform medical research testing in-house, whether for actual testing purposes or quality control checks, DHHS would need to purchase laboratory and analysis equipment, lease or purchase laboratory space, and hire a trained technician(s) to perform the testing. This effort would be substantial and costs would likely outweigh usefulness. Therefore, this fiscal note assumes that all analysis and testing of DNA samples will be outsourced to biotechnology corporations and research institutions in the state. The National Institute of Justice has negotiated a rate of approximately \$50 per sample for the convicted offender DNA samples that many states outsource to private labs. Due to volume considerations, DHHS anticipates that a contract for analysis and testing would cost approximately \$300 per sample. **Without a clear forecast of volunteer participation in this proposed DNA database, this analysis assumes an expenditure range of \$200 to \$300 per sample.**

Translating this per sample expenditure for the analysis and testing contract into an annual expenditure is difficult without knowing the number of volunteers for the DNA database. **Figure 1** displays the annual anticipated expenditure for the contract at different levels of participation by volunteers. These expenditures are based on the assumed cost of \$200 to \$300 per sample.

Figure 1 - Estimated Recurring Contract Cost for DNA Testing and Analysis	
Number of Samples	Annual Expenditure at \$200 - \$300 per sample
1,000	\$200,000 - \$300,000
2,000	\$400,000 - \$300,000
5,000	\$1,000,000 - \$1,500,000
10,000	\$2,000,000 - \$3,000,000

Figure 2 summarizes, in detail, the expenditure assumptions discussed throughout the fiscal note.

Figure 2 - DNA Database Scenario		
Recurring / Non-Recurring	Expenditure	Activities Required by DHHS
Non-Recurring	<ul style="list-style-type: none"> • Web-based Questionnaire - \$30,000 • Database Design - \$25,000 • Storage freezer - \$10,000 • Stain card transfer lab & equipment – <i>unknown</i> TOTAL – at least \$65,000 (+ Stain card lab and equipment costs)	<ul style="list-style-type: none"> • Promotion and advertising • Detailed medical interview/questionnaire creation and data entry with online option • DNA collection kit process • DNA Computer Database requirements • Sample storage in freezer • Stain card transfer • Contract out for medical testing / usage
Recurring	<ul style="list-style-type: none"> • Program Staffing - \$186,477 • Stain card transfer staffing - \$40,000 • Promotional Activities - \$50,000 TOTAL – at least \$276,477 (+ per-sample costs listed below)	
Per-sample Recurring Expenditures	<i>Per Sample -</i> <ul style="list-style-type: none"> • \$5 / collection kit • \$200-\$300 / for testing & analysis 	

Department of Correction

Class 1 Misdemeanor Impact. The Sentencing and Policy Advisory Commission prepares inmate population projections annually.¹ Based on the most recent population projections and estimated available prison bed capacity, *there are no surplus prison beds available for the five year Fiscal Note horizon and beyond.*

Because HB 1256 creates a new offense, the Sentencing Commission does not have any historical data from which to estimate the impact of this bill on the prison population. On average, for every seven convictions of a Class 1 misdemeanor, one offender receives an active sentence averaging 35 days to be served in a local jail. For 30-90 day sentences in local jails, the Department of Correction reimburses the county \$18/day. If sentencing practice for this offense is similar to that of other Class 1 misdemeanors, for every 7 convictions the cost to the State would average \$630 (=35*18). In addition, 82 percent of Class 1 misdemeanor convictions resulted in community sentences, and two percent resulted in intermediate sentences. Average daily cost for supervised non-active punishments range from \$1.83 to \$11.47.

Judicial Branch

For most criminal penalty bills, the Administrative Office of the Courts (AOC) provides Fiscal Research with an analysis of the fiscal impact of the specific bill. For these bills, fiscal impact is typically based on the assumption that court time will increase due to an expected increase in trials and a corresponding increase in the hours of work for judges, clerks and prosecutors. This increased court time is also expected to result in greater expenditures for jury fees and indigent defense.

HB 1256 creates a Class 1 misdemeanor offense for a person who knowingly discloses information in a DNA record or information related to a DNA analysis of a blood specimen except as authorized under the bill. Current G.S. 15A-266.11 makes the unauthorized use of the State DNA Database or Databank a Class 1 misdemeanor. Because the AOC does not have an offense code for current G.S. 15A-266.11, no data is available concerning the frequency of this offense under current law. The lack of an AOC offense code is some indication that these offenses are infrequently charged and/or infrequently result in convictions.

The AOC cannot estimate the number of new charges that would arise as a result of this bill. For Class 1 offenses that are brought to trial, the estimated court cost per trial is \$3,144. For Class 1 offenses not brought to trial, and where a guilty plea is entered, AOC estimates the cost per guilty plea at \$279.

SOURCES OF DATA: Department of Health and Human Services; Department of Justice; Department of Correction; Judicial Branch; North Carolina Sentencing and Policy Advisory Commission; and, Office of State Construction.

¹ The projections used for incarceration fiscal notes and fiscal memos are based on January 2003 projections. These projections are based on historical information on incarceration and release rates under Structured Sentencing, crime rate forecasts by a technical advisory board, probation and revocation rates, and the decline (parole and maxouts) of the stock prison population sentenced under previous sentencing acts.

In estimating the fiscal impact to DHHS, several sources of information were incorporated. Fiscal Research Division consulted with the Department of Justice and the Legislative Information Systems Division (ISD) to formulate the estimated fiscal impact of this proposed bill. Justice was consulted for their experience in managing a convicted offender DNA database through the State Bureau of Investigation. ISD was consulted for their experience in information systems development and management. DHHS provided their anticipated fiscal impacts stemming from this proposed bill. This analysis attempts to strike a balance between all sources of expenditure information.

TECHNICAL CONSIDERATIONS:

1. There are three similar bills (HB 1254, HB 1255, HB 1256) that direct DHHS to establish a DNA database. Each bill has a corresponding fiscal note calculating the establishment of a DNA database separately. However, ultimately only one database would be required within DHHS to fulfill the legislative requirements.
2. In calculating the expenditures for creating and managing the DNA database, potential costs associated with the federal Health Insurance Portability and Accountability Act (HIPAA) were not included. Although DHHS is a covered agency under HIPAA rules, it is unclear at this time whether the records in this database would be subject to HIPAA compliance. If DHHS later finds that these records fall under the HIPAA umbrella, compliance with federal rules could increase the cost of creating and maintaining the database. No estimates are currently available regarding HIPAA's impact.
3. This fiscal analysis is independent of the impact of other criminal penalty bills being considered by the General Assembly, which could also increase the projected prison population and thus the availability of prison beds in future years. The Fiscal Research Division is tracking the cumulative effect of all criminal penalty bills on the prison system as well as the Judicial Department.

FISCAL RESEARCH DIVISION: (919) 733-4910

PREPARED BY: Stephanie Schmitt, Chloe Gossage, and Jim Klingler

APPROVED BY: James D. Johnson, Director, Fiscal Research Division

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