

M00J
Laboratories Administration
Department of Health and Mental Hygiene

Operating Budget Data

(\$ in Thousands)

	<u>FY 11</u> <u>Actual</u>	<u>FY 12</u> <u>Working</u>	<u>FY 13</u> <u>Allowance</u>	<u>FY 12-13</u> <u>Change</u>	<u>% Change</u> <u>Prior Year</u>
General Fund	\$18,846	\$18,691	\$18,338	-\$352	-1.9%
Adjusted General Fund	\$18,846	\$18,691	\$18,338	-\$352	-1.9%
Special Fund	560	575	508	-67	-11.7%
Adjusted Special Fund	\$560	\$575	\$508	-\$67	-11.7%
Federal Fund	4,041	3,249	2,895	-354	-10.9%
Adjusted Federal Fund	\$4,041	\$3,249	\$2,895	-\$354	-10.9%
Reimbursable Fund	465	408	428	20	4.8%
Adjusted Reimbursable Fund	\$465	\$408	\$428	\$20	4.8%
Adjusted Grand Total	\$23,911	\$22,923	\$22,169	-\$754	-3.3%

- The fiscal 2013 allowance decreases by \$754,000, or 3.3%.
- General and special funds decrease by \$352,000 and \$67,000, respectively. Federal funds also decrease by \$354,000, or 10.9%. These decreases are offset by an increase in reimbursable funds (\$20,000).

Note: Numbers may not sum to total due to rounding.

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Personnel Data

	<u>FY 11 Actual</u>	<u>FY 12 Working</u>	<u>FY 13 Allowance</u>	<u>FY 12-13 Change</u>
Regular Positions	233.00	229.00	228.00	-1.00
Contractual FTEs	<u>3.94</u>	<u>3.88</u>	<u>3.88</u>	<u>0.00</u>
Total Personnel	236.94	232.88	231.88	-1.00

Vacancy Data: Regular Positions

Turnover and Necessary Vacancies, Excluding New Positions	11.40	5.00%
Positions and Percentage Vacant as of 12/31/11	7.00	3.06%

- The fiscal 2013 allowance includes 1.0 fewer regular positions than the fiscal 2012 appropriation.

Analysis in Brief

Major Trends

Newborn Screenings Comprise a Vast Majority of Tests: Newborn screenings account for 92% of the tests conducted by the Laboratories Administration but require only 11% of the staff. The remaining 8% of the tests are split between environmental, molecular, virology, immunology, and microbiology tests.

Accuracy of Laboratory Testing: The accuracy evaluation of the laboratory tests was met in three out of four areas.

Changes at the Division of Drug Control: The Division of Drug Control has been able to increase the number of controlled dangerous substance inspections it performs from 180 in fiscal 2007 to 883 in fiscal 2011.

Issues

Destruction of Lead Paint Records: In March 2011, the Department of Health and Mental Hygiene discovered that the Laboratories Administration had destroyed test results from 1985 to 2003 that documented lead poisoning in Maryland children. In June 2011, the Office of the Inspector General at the department released a report regarding the record destruction and recommended several changes at the Laboratories Administration. This issue will summarize the Office of the Inspector General's findings and recommendations.

Role of the Laboratories Administration in Public Health Preparedness: In September 2011, the Centers for Disease Control and Prevention issued its annual report *Public Health Preparedness: State-by-State Update on Laboratory Capabilities and Response Readiness Planning*. In 2011, Maryland was able to meet national standards for biological and chemical laboratory capabilities.

Recommended Actions

1. Concur with Governor's allowance.

Updates

New Public Health Laboratory: The Maryland Economic Development Corporation (MEDCO), in conjunction with the New East Baltimore Partnership, LLC, is responsible for designing, constructing, and operating the new laboratory through a capital lease between the State and MEDCO. State appropriated rent is the source of debt service on the MEDCO issues bonds. Construction of the new laboratories' facility is scheduled to be completed in April 2014.

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Operating Budget Analysis

The mission of the Laboratories Administration is to promote, protect, and preserve the health of the people of Maryland from the consequences of communicable diseases, environmental factors, and unsafe consumer products through the following measures:

- adopting scientific technology to improve the quality and reliability of laboratory practice in the areas of public health and environmental protection;
- expanding newborn hereditary disorder screening;
- maintaining laboratory emergency preparedness efforts; and
- promoting quality and reliability of laboratory data in support of public health and environmental programs.

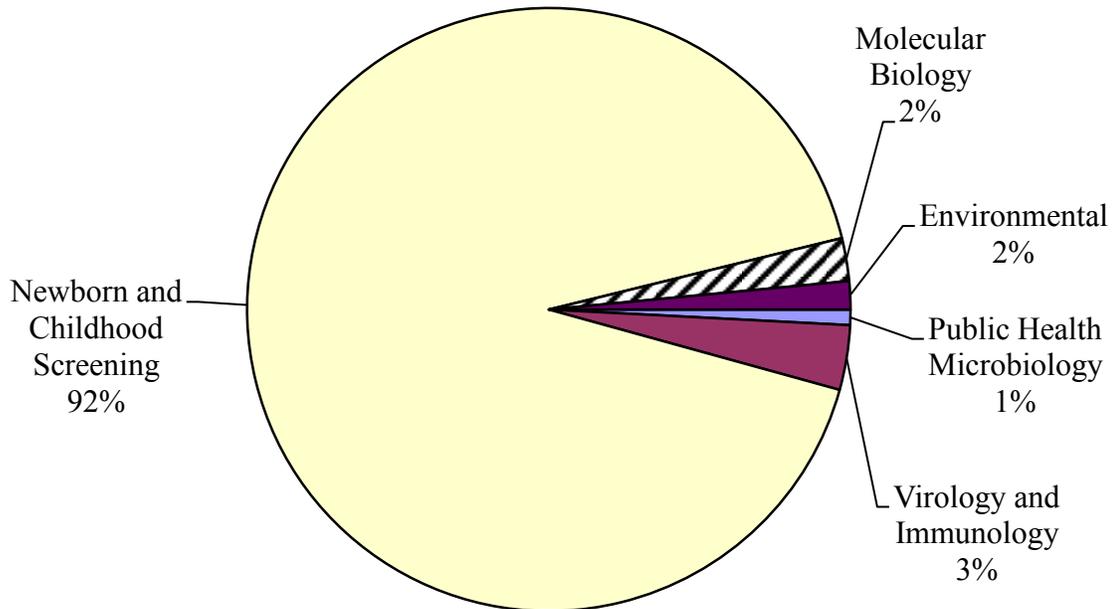
The Department of Health and Mental Hygiene (DHMH) has regional laboratories in Salisbury and Cumberland, in addition to the central laboratory in Baltimore.

Performance Analysis: Managing for Results

Newborn Screenings Comprise a Vast Majority of the Tests

Exhibit 1 shows that newborn and childhood screening account for 92% of the 10.3 million tests conducted by the Laboratories Administration in fiscal 2011, while the remaining 8% of tests are split between environmental, molecular, virology, immunology, and microbiology tests. However, the Newborn and Childhood Screening Division employs only about 11% of the employees within the Laboratories Administration because the tests are heavily automated. Since the other tests are more time consuming and labor intensive, the other divisions of the Laboratories Administration require more staff.

Exhibit 1
Proportion of Laboratory Tests by Type
Fiscal 2012



Source: Department of Health and Mental Hygiene

Commitment to Accuracy

Proficiency testing of the Laboratories Administration’s work demonstrates the administration’s commitment to accuracy. Tests are conducted three or four times a year. Samples are sent to each division from the appropriate federal or oversight agency, including the Centers for Disease Control (CDC), Food and Drug Administration (FDA), and the National Voluntary Laboratory Accreditation program. The samples are tested, and the results are then verified for accuracy. **Exhibit 2** shows that in fiscal 2011, the Laboratories Administration surpassed the stated goal in three of the four categories of testing. However, the administration failed to meet its goals for the infectious bacterial testing division.

Exhibit 2
Accuracy in Proficiency Testing
Fiscal 2006-2011

	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>Goal</u>
Infectious Bacterial Testing	100%	100%	99%	98%	99%	97%	98%
Viral Disease Testing	98%	98%	100%	100%	98%	100%	98%
Environmental Testing	97%	97%	97%	91%	92%	97%	95%
Newborn Screening	100%	100%	100%	100%	100%	99%	98%

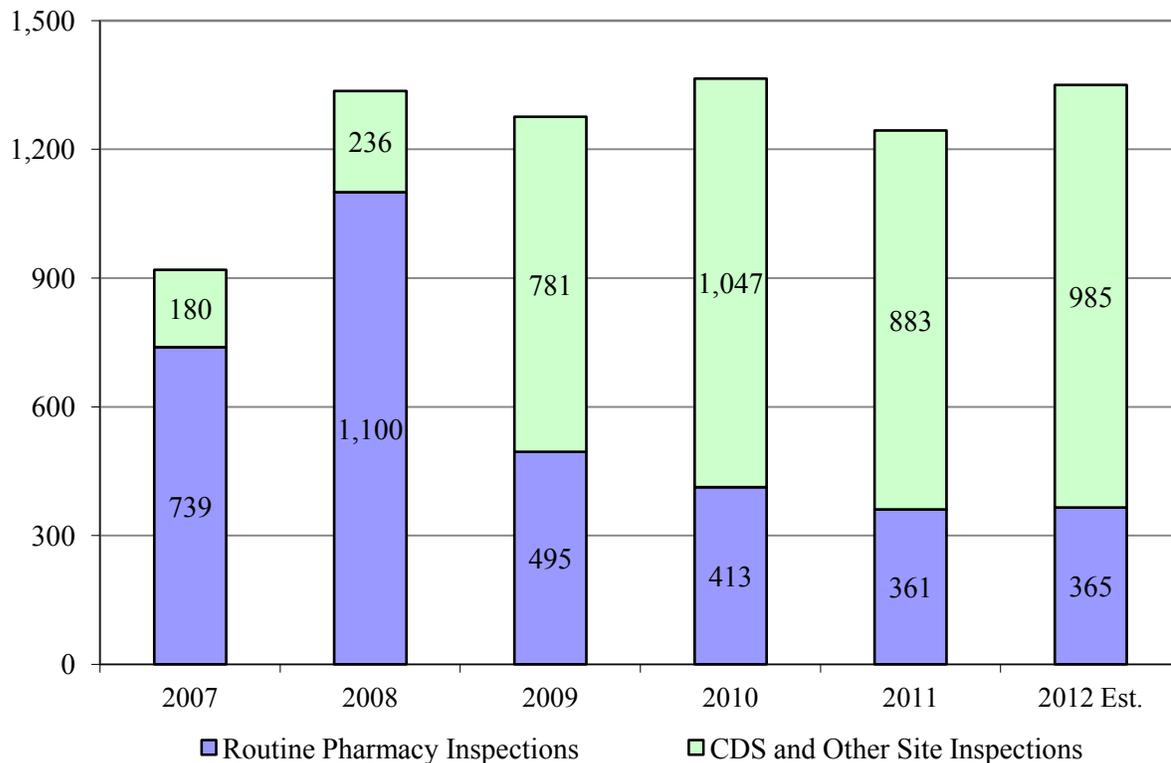
Source: Department of Health and Mental Hygiene

Changes at the Division of Drug Control

The Division of Drug Control registers practitioners and establishments to legally manufacture, distribute, dispense, or otherwise handle controlled dangerous substances (CDS) in Maryland. The federal Controlled Substances Act of 1970 (CSA) authorizes federal regulation of the manufacture, importation, possession, and distribution of certain drugs. Under the CSA, various drugs are listed on Schedules I through V and generally involve drugs that have a high potential for abuse. Schedule I drugs have no acceptable medical use in the United States, and prescriptions may not be written for these substances. Morphine and amphetamines (such as Adderall) are examples of Schedule II drugs; anabolic steroids and hydrocodone are examples of Schedule III drugs; and benzodiazepines (such as Valium or Xanax) are Schedule IV drugs. Schedule V drugs include cough suppressants containing small amounts of codeine and the prescription drug Lyrica, an anticonvulsant and pain modulator. The number of CDS permits processed by the Division of Drug Control has slightly increased from 17,346 in fiscal 2007 to 17,814 in fiscal 2011.

Exhibit 3 shows the number of CDS inspections for pharmacies and nonpharmacy sites. In fiscal 2009, the Board of Pharmacy assumed the responsibility for conducting routine annual inspections of pharmacies, which freed up the Division of Drug Control to focus on other responsibilities, such as inspecting dispensing practitioners and auditing methadone programs and long-term care and assisted living facilities that possess CDS; however, the division still conducts closing inspections of pharmacies, as well as CDS inspections of pharmacies. Pharmacies are required to perform an internal audit of their CDS inventory annually. When performing an inspection, the Board of Pharmacy documents the date of the most recent internal CDS audit and forwards the audit date to the Division of Drug Control. This allows the Division of Drug Control to set priorities for follow-up on CDS inspections of pharmacies. The work of the Board of Pharmacy has allowed the Division of Drug Control to dramatically increase the number of CDS inspections it performs annually for nonpharmacy entities, from 180 in fiscal 2007 to 883 in fiscal 2011.

**Exhibit 3
Division of Drug Control Inspections
Fiscal 2007-2012**



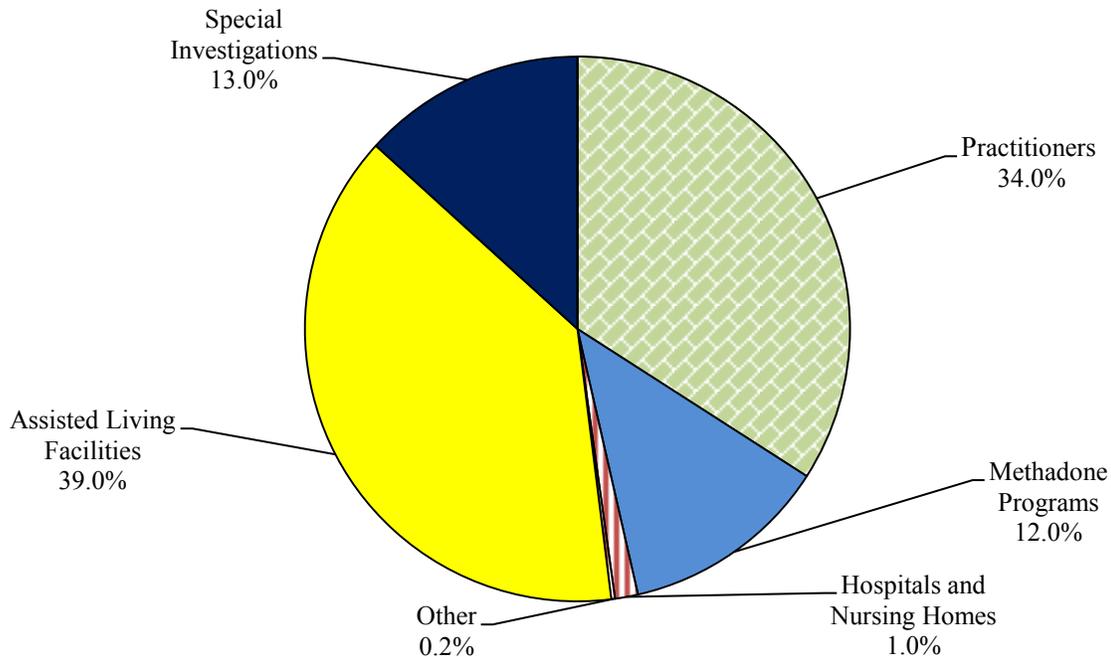
CDS: Controlled Dangerous Substance

Source: Department of Health and Mental Hygiene

Exhibit 4 shows that assisted living facilities account for 39.0% of the 883 nonpharmacy inspections conducted in fiscal 2011. Furthermore, practitioners (physicians, podiatrists, and dentists) accounted for 34.0% of nonpharmacy inspections. According to the respective health occupations boards, a total of 1,265 dispensing permits are held by nonpharmacist practitioners in Maryland including approximately 1,170 physicians, 55 dentists, and 40 podiatrists. Therefore, practitioners are only inspected once every four years. The remaining 27.0% of inspections are split between special investigations (13.0%), methadone programs (12.0%), hospitals and nursing homes (1.0%), and other facilities (0.2%).¹ **The agency should comment on whether the frequency of inspections for dispensing practitioners is sufficient to ensure that practitioners are dispensing CDS in accordance with State and federal regulations.**

¹ Among other things, special investigations include CDS inspections for FDA, the Drug Enforcement Agency, and the Federal Bureau of Investigation.

Exhibit 4
Nonpharmacy CDS Inspections
Fiscal 2011



CDS: Controlled Dangerous Substance

Source: Department of Health and Mental Hygiene

Fiscal 2012 Actions

Section 47 of the fiscal 2012 budget bill required the Governor to abolish 450 positions as of January 1, 2012. The Laboratories Administration's share of the reduction was 3 positions. The annualized salary savings due to the abolition of these positions is expected to be \$132,857 in general funds.

Proposed Budget

As shown in **Exhibit 5**, the Governor's proposed allowance for fiscal 2013 decreases by \$0.8 million, or 3.3%, over the fiscal 2012 working appropriation. As the exhibit demonstrates, the general fund support decreases by \$0.4 million, or 1.9%; special fund support decreases by \$0.1 million, or 11.7%; federal fund support decreases by \$0.4 million, or 10.9%; and reimbursable fund support increases by \$20,000, or 4.8%.

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**Exhibit 5
Proposed Budget
DHMH – Laboratories Administration
(\$ in Thousands)**

How Much It Grows:	<u>General Fund</u>	<u>Special Fund</u>	<u>Federal Fund</u>	<u>Reimb. Fund</u>	<u>Total</u>
2012 Working Appropriation	\$18,691	\$575	\$3,249	\$408	\$22,923
2013 Allowance	<u>18,338</u>	<u>508</u>	<u>2,895</u>	<u>428</u>	<u>22,169</u>
Amount Change	-\$352	-\$67	-\$354	\$20	-\$754
Percent Change	-1.9%	-11.7%	-10.9%	4.8%	-3.3%
 Contingent Reduction	 \$0	 \$0	 \$0	 \$0	 \$0
Adjusted Change	-\$352	-\$67	-\$354	\$20	-\$754
Adjusted Percent Change	-1.9%	-11.7%	-10.9%	4.8%	-3.3%
 Where It Goes:					
Personnel Expenses					
Employee retirement					\$241
Employee and retiree health insurance.....					95
Other fringe benefit adjustments					-1
Turnover adjustments.....					-4
Social Security contributions					-6
Salary expenses					-56
One transferred position.....					-90
Removal of fiscal 2012 one-time \$750 bonus.....					-177
Other Changes					
Costs for contractual laboratory services					-18
Trash removal costs.....					-21
One-time laboratory equipment purchases.....					-105
Capital lease payments for laboratory equipment					-111
Funding for a part-time clinical geneticist and a full-time genetic counselor at the University of Maryland Baltimore under the Newborn Screening Program.....					-250
Costs for laboratory supplies and chemicals					-251
Total					-\$754

Note: Numbers may not sum to total due to rounding.

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Personnel

Personnel expenditures increase by \$2,000 in fiscal 2013. Employee retirement contributions increase by \$241,000, and employee and retiree health insurance expenses increase by \$95,000. These increases are offset by decreases in other fringe benefits (\$1,000), increased turnover adjustments (\$4,000), Social Security contributions (\$6,000), and regular earnings due to the annualized savings from previously abolished positions (\$56,000). The fiscal 2013 allowance also transfers 1 position from the Laboratories Administration to the Family Health Administration to support the Newborn Screening Program. This transfer decreases the budget for the Laboratories Administration by \$90,000. Finally, the budget decreases by \$177,000 due to the removal of funds associated with the fiscal 2012 one-time \$750 bonus.

Other Changes

A major reduction to the fiscal 2013 allowance is a \$251,000 decrease in funds for laboratory supplies and chemicals. The majority of this decrease occurs in the Public Health Emergency Preparedness (\$122,000), Human Immunodeficiency Virus (HIV) Viral Load Testing (\$51,000), and the Chlamydia Control (\$41,000) programs. The fiscal 2013 allowance also eliminates funding for a part-time physician clinical geneticist, a full-time genetic counselor, and back-up medical on-call service from the University of Maryland, Baltimore (\$250,000) for newborn screening follow-up. The follow-up program facilitates the rapid identification and treatment of affected infants under the Newborn Screening Act (Chapter 256 of 2008). Funding for these services are now budgeted within the Family Health Administration. Finally, the budget decreases by \$111,000 for capital lease payments for laboratory equipment and \$105,000 for laboratory equipment for food chemistry and microbiology.

Revenue Assumptions

The Governor's fiscal 2013 budget plan assumes an additional \$1,360,000 in general fund revenues from the Laboratories Administration. General fund revenues are expected to increase due to an increase in the newborn screening fee. Presently, the fee is set in the *Code of Maryland Regulations* at \$70. This increase in revenues is based on the assumption that the department will amend its regulations to increase fees to \$90. This is the first time the newborn screening fee has been raised since 2009.

Issues

1. Destruction of Lead Paint Records

In March 2011, DHMH discovered that the Laboratories Administration had destroyed test results from 1985 to 2003 that documented lead poisoning in Maryland children. In June 2011, the Office of the Inspector General (OIG) at the department released a report regarding the record destruction and recommended several changes at the Laboratories Administration. OIG had two main findings. The first finding was that records under subpoena were destroyed by two individuals at the Laboratories Administration. The second finding indicated that the record destruction was, to a significant extent, caused by resource shortages, logistical problems, and a lack of attention by management to address backlogs within the Laboratories Administration. Based on its findings, OIG had four recommendations:

- the process for responding to requests and providing blood lead records should be automated, simplified, and updated to ensure both timely responses to requests for records and the overall integrity of the system;
- an electronic method to log and track the requests for lead testing should be pursued by the Laboratories Administration;
- all duties involved in processing the blood lead test records should be segregated from responding to data requests, and all duties in processing and responding to the requests should be segregated among staff; and
- the department should consider relocating this process to the Maryland Department of the Environment (MDE).

It is important to note that the administration has made significant progress in implementing the OIG's recommendations. The administration's information technology group developed an electronic tracking system in the Laboratory Information System, and implementation is in progress. The administration is also investigating the cost of procuring document management systems, scanners, storage drives, and document management software to store and retrieve existing paper blood and environmental test records to completely automate the blood-lead testing process. Furthermore, the duties in the process of responding to subpoenas or requests for information for blood lead test results have been segregated among different individuals. Additional quality assurance measures have also been implemented. The department advises that there are no plans this fiscal year to transfer administrative control of the lead registry to MDE.

2. Role of the Laboratories Administration in Public Health Preparedness

CDC issued its annual report *Public Health Preparedness: State-by-State Update on Laboratory Capabilities and Response Readiness Planning* in September 2011. The report, which documents progress in two important preparedness activities, laboratory capabilities and response readiness and planning, will be fully discussed in the analysis for the Office of Preparedness and Response; however, one of the two areas outlined in the report relates to the functioning of public health laboratories.

The report noted that biological laboratory capacities were strong in most states and localities. Overall, biological laboratories improved their abilities to rapidly identify certain disease-causing bacteria (often implicated in foodborne disease outbreaks) and send reports to CDC. For example, the number of states that submitted at least 90% of E. coli test results to CDC's PulseNet database within four working days of receiving the samples increased from 29 in 2008 to 38 in 2010. In Maryland, 100% of the test results were forwarded within four working days, up from 95% in 2008. In addition, Laboratory Response Network (LRN) biological laboratories maintained a high test pass rate for detecting other biological agents – the pass rate was consistently above 90% from 2008 to 2010. Maryland's performance was consistent with the national trend with a 94% pass rate.

CDC noted that LRN chemical laboratories also increased their abilities to rapidly detect and quantify chemical agents. The average total number of methods successfully demonstrated by the more advanced LRN laboratories (Levels 1 and 2), to rapidly detect chemical agents during proficiency testing, rose from 6.7 methods in 2009 to 8.9 methods in 2010. In 2010, Maryland had a total of 8.0 methods. These methods are important for determining how widespread an incident was, identifying individuals needing treatment, and helping law enforcement officials determine the origin of the agent. Furthermore, in a 2010 LRN Emergency Response Proficiency Test exercise, 17 out of 17 unknown chemical agents were correctly identified. In 2009, only 11 out of 14 agents were correctly identified.

Recommended Actions

1. Concur with Governor's allowance.

Updates

1. New Public Health Laboratory

The construction of a new public health laboratory will include space for six laboratory divisions, support services, and administrative functions. The existing facility has several problems, including insufficient space; a deteriorated building infrastructure that results in poor environmental conditions and high risk of operations shut-downs; and a facility design and location which pose security risks and potential health risks to occupants of the laboratory tower and the surrounding community.

The Maryland Economic Development Corporation (MEDCO), in conjunction with the New East Baltimore Partnership, LLC, is responsible for designing, constructing, and operating the new laboratory through a capital lease between the State and MEDCO. State appropriated rent is the source of debt service on the MEDCO issues bonds. Construction of the new laboratories' facility has begun and is scheduled to be completed in April 2014. The agency anticipates transitioning to the new facility in June 2014. DHMH advises that annual debt service will be \$6.2 million in 2014 and \$13.9 million in fiscal 2015. In addition, annual operating costs are estimated to be \$3.7 million and \$7.2 million in fiscal 2014 and 2015, respectively.

Current and Prior Year Budgets

**Current and Prior Year Budgets
DHMH – Laboratories Administration
(\$ in Thousands)**

	<u>General Fund</u>	<u>Special Fund</u>	<u>Federal Fund</u>	<u>Reimb. Fund</u>	<u>Total</u>
Fiscal 2011					
Legislative Appropriation	\$18,846	\$481	\$3,308	\$440	\$23,075
Deficiency Appropriation	0	0	1,091	0	1,091
Budget Amendments	0	105	0	25	130
Reversions and Cancellations	0	-26	-358	0	-384
Actual Expenditures	\$18,846	\$560	\$4,041	\$465	\$23,911
Fiscal 2012					
Legislative Appropriation	\$18,537	\$575	\$3,227	\$408	\$22,746
Budget Amendments	154	0	23	0	177
Working Appropriation	\$18,691	\$575	\$3,249	\$408	\$22,923

Note: Numbers may not sum to total due to rounding.

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Fiscal 2011

The budget for the Laboratories Administration closed at \$23.9 million, an increase of \$0.8 million above the original legislative appropriation. Special funds increased by \$105,000 to cover additional testing services performed for local health departments. Reimbursable funds increased by \$25,000 for the Deep Creek Lake Water Quality Monitoring Program. These funds are available through the Department of Natural Resources.

Deficiency appropriations increased the legislative appropriation by \$1.1 million in federal funds. Federal funds were needed for public health and emergency preparedness (\$521,905), food safety cooperative agreements (\$208,707), food safety and security monitoring (\$115,468), family planning services (\$69,000), prescription drug monitoring (\$43,468), and epidemiology and laboratory capacity (\$132,204).

In total, the Laboratories Administration cancelled \$0.4 million at the end of fiscal 2011. Special funds were cancelled due to a decrease in laboratory testing for local health departments (\$25,978). Federal funds were cancelled due to unattained federal funds for HIV activities (\$357,832).

Fiscal 2012

The fiscal 2012 working appropriation is \$22.9 million, an increase of \$0.2 million over the original legislative appropriation. The fiscal 2012 budget for the Department of Budget and Management (DBM) included centrally budgeted funds for the \$750 one-time bonus for State employees. This resulted in the transfer of funds from DBM to the Laboratories Administration (\$154,137 in general funds and \$22,596 in federal funds).

**Object/Fund Difference Report
DHMH – Laboratories Administration**

<u>Object/Fund</u>	<u>FY 11 Actual</u>	<u>FY 12 Working Appropriation</u>	<u>FY 13 Allowance</u>	<u>FY 12 - FY 13 Amount Change</u>	<u>Percent Change</u>
Positions					
01 Regular	233.00	229.00	228.00	-1.00	-0.4%
02 Contractual	3.94	3.88	3.88	0.00	0%
Total Positions	236.94	232.88	231.88	-1.00	-0.4%
Objects					
01 Salaries and Wages	\$ 16,653,458	\$ 16,710,044	\$ 16,711,948	\$ 1,904	0%
02 Technical and Spec. Fees	133,448	114,056	111,167	-2,889	-2.5%
03 Communication	135,525	138,997	124,389	-14,608	-10.5%
04 Travel	45,051	6,299	30,000	23,701	376.3%
07 Motor Vehicles	18,579	26,420	16,828	-9,592	-36.3%
08 Contractual Services	1,223,125	1,494,310	1,074,630	-419,680	-28.1%
09 Supplies and Materials	4,704,739	4,277,211	4,033,418	-243,793	-5.7%
10 Equipment – Replacement	39,608	0	0	0	0.0%
11 Equipment – Additional	855,326	105,000	0	-105,000	-100.0%
12 Grants, Subsidies, and Contributions	30,000	0	0	0	0.0%
13 Fixed Charges	72,622	50,559	66,359	15,800	31.3%
Total Objects	\$ 23,911,481	\$ 22,922,896	\$ 22,168,739	-\$ 754,157	-3.3%
Funds					
01 General Fund	\$ 18,845,952	\$ 18,690,675	\$ 18,338,390	-\$ 352,285	-1.9%
03 Special Fund	559,831	574,815	507,615	-67,200	-11.7%
05 Federal Fund	4,040,670	3,249,104	2,894,863	-354,241	-10.9%
09 Reimbursable Fund	465,028	408,302	427,871	19,569	4.8%
Total Funds	\$ 23,911,481	\$ 22,922,896	\$ 22,168,739	-\$ 754,157	-3.3%

Note: The fiscal 2012 appropriation does not include deficiencies.