



STATE OF MARYLAND
DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – Joshua M. Sharfstein, M.D., Secretary

June 17, 2014

The Honorable Martin O'Malley
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: Final Report of the Workgroup on Cancer Clusters and Environmental Causes of Cancer

Dear Governor O'Malley, President Miller, and Speaker Busch:

Pursuant to Senate Bill 380 (Chapter 248 of the Acts of 2013)/House Bill 1343 (Chapter 249 of the Acts of 2013), the Workgroup on Cancer Clusters and Environmental Causes of Cancer (Workgroup) submits this report on the findings and recommendations of the Workgroup related to: 1) the process that State agencies use to research and identify cancer clusters in the State; 2) communication between State agencies and between State and federal agencies regarding research about and the identification of cancer clusters and potential environmental causes of cancer; 3) research being conducted by the academic medical institutions in the State on potential cancer clusters and how findings from this research are communicated to the appropriate State and federal agencies; and 4) whether additional information regarding potential cancer clusters and potential environmental causes of cancer should be provided in annual reports to the public.

I hope this information is useful. If you have questions about this report, please contact Workgroup Co-Chair Courtney Lewis at 410-767-0824 or courtney.lewis@maryland.gov.

Sincerely,

Joshua M. Sharfstein, M.D.
Secretary

Enclosure

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**REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY BY THE
WORKGROUP ON CANCER CLUSTERS AND ENVIRONMENTAL CAUSES
OF CANCER**

**SENATE BILL 380 (CHAPTER 248 OF THE ACTS OF 2013)
HOUSE BILL 1343 (CHAPTER 249 OF THE ACTS OF 2013)**

Department of Health and Mental Hygiene

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I. Executive Summary

In July 2013, the Department of Health and Mental Hygiene (DHMH), in consultation with the Maryland Department of the Environment (MDE), convened an 18 member Workgroup (Appendix A) on Cancer Clusters and Environmental Causes of Cancer (Workgroup) to examine issues relating to the investigation of potential cancer clusters in the State and potential environmental causes of cancer pursuant to SB 380 (Chapter 248 of the Acts of 2013)/House Bill 1343 (Chapter 249 of the Acts of 2013).

Seven meetings of the Workgroup were held between July 23, 2013 and December 5, 2013 (Appendix B) to address the charge to the Workgroup. Speakers from DHMH, MDE, and local health departments (LHDs) presented the existing statutes, regulations, and procedures for regulating, reporting, and investigating environmental causes of cancer. Speakers with additional expertise in the agenda topics presented relevant information. Findings relevant to each of the topical areas were summarized in this report (see pages 20-25).

The Workgroup's findings were not prioritized, but covered a broad range of issues related to the investigation of public concerns about cancer. Some of the findings include:

- Cancer is not one disease but a group of diseases characterized by uncontrolled growth and spread of abnormal cells. Cancer as a whole is relatively common, but specific types of cancer range greatly in their incidence and prevalence. Generally, with the exception of childhood cancers, age is the strongest risk factor for adult forms of cancer.
- Currently in Maryland, cancer clusters or cancer concerns are raised by one or more residents and reported to the State or LHDs; proactive identification of cancer clusters is not done.
- Federal agencies are not routinely involved in cancer cluster investigations when reports are received by states. Neither is there routine communication of cancer cluster reports by Maryland to any federal agency.
- Exposure prevention efforts could benefit from the availability of robust methods to assess cumulative exposure of vulnerable populations. The Workgroup heard that there are substantial methodologic and regulatory challenges to considering cumulative exposures, although these cumulative exposures may be very important.
- There have been few actual cancer clusters identified nationally, despite hundreds of investigations, and it is rare to identify any clusters associated with an environmental exposure or cause. In Maryland in at least the past seven years, no confirmed cancer clusters have been identified among those reported to DHMH.
- Some improvements in timeliness, completeness, accuracy, and collection of additional data on each case reported in the Maryland Cancer Registry (MCR) may be possible, but

would require a considerable investment of time and money. More rapid reporting might improve the MCR's ability to confirm the diagnosis of a reported case of cancer.

- There are opportunities to provide additional information to the public regarding cancer rates, cluster reports, and potential environmental contributions to cancer at the State, county, or sub-county levels through annual reports and other information channels such as online data access and existing web sites. This information might help to alleviate public concerns about cancer clusters or to increase public satisfaction with the investigation of such concerns. Additional funding could enhance the development and dissemination of additional information.

Based on the findings, the Workgroup makes the following recommendations:

Summary of Recommendations of the Workgroup on Cancer Clusters and Environmental Causes of Cancer (see pages 26-29 for full recommendations)

Note: The following recommendations were not prioritized by the Workgroup. The order in which they appear does not indicate their relative importance or priority.

A. To identify, investigate, and assess potential cancer clusters when the public reports cancer clusters or cancer occurrences of concern:

Recommendation A1: DHMH should update and enhance its “Guidelines for the Management of Inquiries Related to Cancer Concerns or suspected Cancer Clusters, January 2010” (Maryland’s Guidelines) by incorporating: a) the 2013 “Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists,” b) alternative approaches to investigation, and c) suggestions of the Workgroup.^{1,2,3}

Recommendation A2: DHMH should more clearly identify the criteria and process it will use to determine when and how far to proceed with investigating a report of a cancer cluster received from the public or a healthcare provider.

Recommendation A3: DHMH MCR should determine the feasibility of improving the data on each reportable tumor in the database or on a subset of cases of environmental concern (sentinel cases) to include more exposure information such as past residential addresses, and occupation information.

¹ “Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists,” *MMWR*, 62(2013), CDC, January 2014, <<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6208a1.htm>>.

² M Goodman et al., “Cancer clusters in the USA: What do the last twenty years of state and federal investigations tell us?” *Critical Reviews in Toxicology*, 42(2012):474-90, PubMed, January 2014, <<http://www.ncbi.nlm.nih.gov/pubmed/22519802>>.

³ Michael Coory and Susan Jordan, “Assessment of chance should be removed from protocols for investigating cancer clusters,” *Intl J Epi*, 42(2013):440-447, *Oxford Journals*, January 2014, <<http://ije.oxfordjournals.org/content/42/2/440.full>>.

Recommendation A4: Have an advisory committee of DHMH Center for Cancer Prevention and Control review DHMH cancer cluster responses to ensure consistency and potentially to improve the investigation methods and processes.

B. To use existing data to identify cancer clusters or cancer occurrences of concern:

Recommendation B1: Collaborate with academic medical institutions and Federal agencies on approaches to the identification, evaluation, and investigation of cancer clusters or cancers of concern that are identified by DHMH.

Recommendation B2: DHMH should convene a group* to:

- Determine what sentinel events could be actively surveyed using MCR data;
- Explore and suggest investigation approaches regarding a) potential exposures in the State to environmental factors that are known to cause cancer (particularly carcinogenic chemicals or ionizing radiation), b) geographic areas of concern for potential exposures, or c) increased observed cancer rates; and
- Explore analytic methods and criteria to determine whether there are geographic areas in Maryland with disparities in exposure or potential exposure to environmental hazards that are known or suspected to cause cancer (particularly carcinogenic chemicals or ionizing radiation). Where such areas are found, explore whether an assessment of risk associated with the exposure should be undertaken.

*The Workgroup agreed that, given the Workgroup's scope of work, time limitations, and the need for input from others with different expertise, these tasks are better suited for a separate group whose responsibilities are limited to only these specific tasks.

C. To educate the public about exposure to and risk from environmental factors that are known to cause cancer; to prevent exposures:

Recommendation C1: With additional funding, DHMH's Environmental Health Bureau (EHB) and MDE should improve access to cancer data and environmental data by publishing maps of cancer rates that also include the capacity to show environmental information such as environmental monitoring data, or sites listed on the National Priority List or Toxic Release Inventory.

Recommendation C2: With additional funding, enhance the EHB web site to include public information regarding 1) environmental factors that cause or contribute to cancer and 2) prevention of cancer by reducing such exposures.

Recommendation C3: Maryland should expand efforts on prevention strategies aimed at reducing exposures to known carcinogens such as considering models from other states, considering legislation to enhance prevention of exposure, working to strengthen the federal Toxic Substances Control Act (TSCA), and educating the public.

Recommendation C4: Given public concerns about drinking water and the risk of cancer, MDE and DHMH should: 1) work together to increase public awareness of existing water supply testing requirements and other regulatory measures designed to ensure safe drinking water; and 2) consider whether changes to existing testing requirements for private wells are advisable.

D. To research potential cancer clusters:

Recommendation D1: Establish a mechanism for information sharing and collaboration among researchers, DHMH MCR and EHB, MDE, and other public health programs in Maryland. In particular, create opportunities for regular exchange of information between researchers and public health and environmental agencies regarding public concerns and inquiries, environmental monitoring, and advances in understanding of cancer mechanisms.

E. To communicate to the public through annual reports:

Recommendation E1: The MCR Cancer Incidence and Mortality Report could include the number of cancer concerns reported to DHMH and the outcome of those reports. This report would be publicly available on DHMH web sites.

Recommendation E2: If DHMH and MDE develop a systematic approach to chemicals of concern as called for in Recommendation C3, the approach should include an annual public report on processes and findings.

F. To maintain and enhance necessary resources:

Recommendation F1: Maintain funding for cancer investigation and outreach-related activities in DHMH EHB and MCR.

Recommendation F2: Increase funding to DHMH and MDE to implement the Workgroup's recommendations regarding enhanced health education messaging about cancer prevention, environmental carcinogens, and exposures of concern, and to enable additional collection, analysis, and/or presentation of data.

II. Background and Charge to the Workgroup

Maryland SB 380 (Chapter 248 of the Acts of 2013)/House Bill 1343 (Chapter 249 of the Acts of 2013), requires the Department of Health and Mental Hygiene (DHMH), in consultation with the Maryland Department of the Environment (MDE), to convene a Workgroup on Cancer Clusters and Environmental Causes of Cancer (Workgroup) to examine issues relating to the investigation of potential cancer clusters in the State and potential environmental causes of cancer, including:

1. The process that State agencies use to research and identify cancer clusters in the State;
2. Communication between State agencies and between State and federal agencies regarding research about and the identification of cancer clusters and potential environmental causes of cancer;
3. Research being conducted by the academic medical institutions in the State on potential cancer clusters and how findings from this research are communicated to the appropriate State and federal agencies; and
4. Whether additional information regarding potential cancer clusters and potential environmental causes of cancer should be provided in annual reports to the public.

The enacted statute further directs DHMH to report the findings of the Workgroup required under this section and any recommendations of the Workgroup to the Governor and the General Assembly.

Pursuant to SB 380/HB 1343, a Workgroup was formed and began meeting in July, 2013. A list of Workgroup members is included in Appendix A. Seven Workgroup meetings were held from July 2013 through December 2013 (Appendix B). Meetings included presentations from experts and discussion by Workgroup members. Each Workgroup meeting also included a designated period of time for public comment. Public comment was also received after Workgroup meetings via e-mail.

In addition to the public comment period held during all Workgroup meetings, DHMH requested public comment on specific questions on the DHMH web site from July 19, 2013 through September 3, 2013. The Request for Public Comment is included in Appendix C. No public comments were received by September 3, 2013 in response to this posting.

The initial draft of the Workgroup report was prepared by DHMH staff, including the Workgroup co-chairs, in consultation with MDE and the Workgroup. The initial draft was reviewed by the entire Workgroup. Following the review of the draft report by the Workgroup, a public comment period was provided during the period from May 9, 2014 through May 27, 2014. There were no comments from the public received during that period.

III. Definitions

A. **Cancer Cluster:**

The Centers for Disease Control and Prevention (CDC) defines a **cancer cluster** as "a greater than expected number of cancer cases that occurs within a group of people in a geographic area over a defined period of time."⁴ Further, the cancer cases are all of the same type except in rare situations where multiple cancer types may be considered when a known exposure is linked to more than one cancer type or when more than one contaminant or exposure type has been identified.

The Workgroup decided to exclude consideration of potential occupational cancer clusters. The Workgroup focused on non-occupational cancer, and the legal, regulatory, and jurisdictional issues related to occupational cancer concerns, which are very different than those involved in non-occupational cancer concerns.

B. **Carcinogen:**

A **carcinogen** is any substance or exposure that can cause cancer.⁵ In this report, the term "known carcinogen" refers to a substance or agent that is generally accepted as a carcinogen based on established scientific evidence.

C. **Environmental Factors:**

Population studies have revealed patterns and specific factors that increase risk of cancer for groups of people. Environmental factors may be defined as all factors affecting the development of cancer beyond inherited or genetic factors. These environmental factors include tobacco, diet, weight, physical activity, certain infections, some occupational exposures, and exposures over which individuals have limited personal control. Collectively these environmental factors are involved to some degree in 2 of 3 (67%) cancers, both alone and in combination with inherited factors.⁶

The Workgroup has limited the definition of environmental factors and the scope of this report. For the purposes of this report, **an environmental factor** is defined as a chemical (ionizing and non-ionizing radiation) or biologic agent in air, water, soil, food, consumer product, or building (home, school, worksite) that causes or promotes cancer and over which an individual has relatively limited personal control over his/her exposure.

Not included in the scope of this report are environmental factors whose exposure is addressed on an individual basis, such as tobacco use, diet, physical activity, and exposure to the sun and artificial ultraviolet radiation, or on an occupational basis. This definition is consistent with the requiring statute.

⁴ *ID* fn 1.

⁵ "Known and probably human carcinogens," 17 October 2013, American Cancer Society, January 2014, <<http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens>>.

⁶ "What is the environment?" 4 November 2010, NCI, January 2014, <<http://www.cancer.gov/cancertopics/understandingcancer/environment/page2>>.

Note: Steps involved in investigations of cancer concerns include:

- Reporting a cancer concern by a citizen or community group to a public health entity;
- Identifying the cases and the area of concern as a “cancer cluster” (defined as an increase in the rate of a specific cancer in a specific population over a period of time and in a particular geographic area);
- Seeking to attribute the cancer cluster to a specific causative or promoting environmental factor;
- Determining whether the cases had exposure to the specific causative or promoting environmental factor; and
- Determining what to do about the specific causative or promoting environmental factor in the environment.

Although occupational exposures and exposures to environmental radon or other natural sources of carcinogens are not included within the scope of this report, an investigation into a cancer concern may point to these as exposure source(s) linked to cancer and be reported as such.

D. Environmental Justice:

Environmental justice is equal protection from environmental and public health hazards for all people regardless of race, income, culture, and social class. Additionally, environmental justice means that no group of people including racial, ethnic, or socioeconomic groups should bear a disproportionate share of the negative environmental consequences resulting from industrial, land-use planning and zoning, municipal and commercial operations, or the execution of federal, state, local, and municipal program and policies.⁷

E. Research and Human Subjects Research versus Investigation:

To distinguish a cancer cluster investigation from research that might require Institutional Review Board (IRB) approval, the Workgroup developed the following definitions based on the U.S. Department of Health and Human Services regulations:

Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. A **systematic investigation** is an activity that involves a prospective plan that incorporates quantitative and/or qualitative data collection, and data analyses to answer a question.

Examples of systematic investigations include:

- Surveys and questionnaires;
- Interviews and focus groups;
- Analyses of existing data or biological specimens;
- Epidemiological studies;
- Evaluations of social or educational programs;

⁷ “Environmental Justice in Maryland,” MDE, January 2014, <http://www.mde.maryland.gov/programs/CrossMedia/EnvironmentalJustice/EJImplementationinMaryland/Pages/Programs/MultimediaPrograms/Environmental_Justice/implementation/details.aspx>.

- Cognitive and perceptual experiments; and
- Medical chart review studies.

Investigations designed to develop or contribute to generalizable knowledge are those designed to:

- Draw general conclusions;
- Inform policy; or
- Generalize findings beyond a single individual or an internal program (e.g., publications or presentations).

Human Subjects Research is a systematic investigation including intervention and interaction with human subjects.

A project that is both research and involves human subjects requires IRB review. In order to ensure the rights, welfare, and protection of all subjects, all human subject research, and all other activities which in part involve human subject research, regardless of sponsorship, must be reviewed and approved by an IRB prior to initiation. This includes all interventions and interactions with human subjects for research, including advertising, recruitment and/or screening of potential subjects.

Examples of research include:

Basic Research

- Toxicology-systematic investigation of the effects of chemicals;
- Genetics-investigation into the DNA sequence of genes associated with cancer;
- Research into methods of investigation of cancer clusters (e.g., statistical methods to identify clusters or to demonstrate associations that are beyond chance); and
- Research into carcinogens and effect of carcinogens on cells/animals/humans;

Human Subjects Research

- Long term follow-up of cohorts of people (groups of individuals identified for follow-up [e.g., doctors, nurses, respondents to calls for volunteers, people infected with Human Immunodeficiency Virus, residents of communities, etc.]) with collection of exposure information and health outcomes (including cancer);
- Long term follow-up of people with identified exposure or potential exposure to known carcinogens (occupational cohorts);
- IRB-approved access to Maryland Cancer Registry (MCR) data to address research questions; and
- Further epidemiologic study of area or population that a researcher may be contracted to investigate.

Investigation is the study of questions posed that are under the authority and regulatory responsibility of state and local governmental agencies whose mission is to protect the public's health. These investigations are distinguished from research studies and generally

do not require informed consent of those involved in the investigation and do not require IRB approval. Investigation may also be a category of "applied research."

Example categories include:

- Investigation of questions reported to public health authorities and raised by the public or others about **carcinogen exposure concerns**;
- Investigation of questions reported to public health authorities and raised by the public or healthcare providers about **specific cancer concerns**;
- Investigation of questions raised by the public or others about carcinogen exposures and reported to academic researchers;
- Investigation of questions raised by DHMH in response to routine ongoing analysis/evaluation of MCR data;
- Investigation of novel or new ways of looking at MCR data or environmental data to prospectively identify cancer clusters/cancer trends;
- Investigation to prospectively identify and respond to cancer clusters (this may be basic research and require IRB approval if the investigation requires release of MCR data); and
- Investigation of concerns raised by discovery and mapping of environmental carcinogen contamination with potential for exposure.

IV. Statutes, Regulations, and Executive Orders Governing the Environment, Disease Investigation, Cancer Reporting, and Data Release in Maryland

There are numerous statutes, regulations, and executive orders in Maryland that govern the protection from exposure to environmental hazards, disease reporting, investigation, and data release. These include, but are not limited to, the following:

A. Maryland statutes and regulations protecting the environment and preventing exposure to environmental hazards (including chemicals and radiation):

MDE Environmental Regulations web site, which includes links to resources for State and Federal statutes and regulations that govern MDE activities,
<http://www.mde.state.md.us/programs/regulations/Pages/index.aspx>.

MDE web site, which includes links to landing pages for air, water, land, and public health,
<http://mde.maryland.gov>.

B. Maryland statute governing lab examination and disease reporting:

Md. Ann. Code Health-General Art. §18-205.

C. Maryland regulations regarding disease reporting:

Code of Maryland Regulations (COMAR) 10.06.01.03 Reportable Diseases, Conditions, Outbreaks, and Unusual Manifestations; Submitting Clinical Materials, states, in part:

“A. A person, as set forth in Regulation .04 of this chapter, shall report the diseases or conditions listed in §C of this regulation, or any other condition as requested by the Secretary.

B. Within 1 working day of a positive laboratory finding for a disease or condition listed in §C of this regulation, or upon request of the Secretary, the director of a medical laboratory shall:

- (1) Submit clinical material to the Department's public health laboratory; and
- (2) Include information about the clinical material on a form provided by the Secretary.

C. List of Reportable Diseases and Conditions.

**HEALTH CARE PROVIDERS, INSTITUTIONS, AND OTHERS¹
 LABORATORIES
 TIMEFRAME FOR REPORTING²**

Diseases and Conditions	Laboratory Evidence of	Submit Clinical Materials to the Department ³	Immediate	Within 1 Working Day
(1) An outbreak of a disease of known or	Similar etiological agents from a		X	

unknown etiology that may be a danger to the public health ⁴	grouping or clustering of patients			
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1. As required to report in Regulation.04A(1)-(3), (5), and (6) of this chapter.
2. The timeframe for reporting is specified in Regulation .04C of this chapter.
3. Clinical material shall be submitted to §B of this regulation.
4. Any grouping or clustering of patients having similar disease, symptoms, or syndromes that may indicate the presence of a disease outbreak.”

D. Maryland statute governing the reporting of cancer cases:

Md. Ann. Code Health-General Art. §18-203 states:

Notwithstanding any other provision of law, the Department may provide patient-identifying information for patients treated in this State for cancer to a cancer control agency in another state if:

- (1) The patient is a resident of the other state;
- (2) The Department determines that the agency will preserve the confidentiality of the information; and
- (3) The other state has authority to provide equivalent information on Maryland residents to this State.

Md. Ann. Code Health-General Art. §18-204, states:

“(b)(1) Each hospital which has care of a patient with cancer or a central nervous system tumor, each freestanding laboratory, freestanding ambulatory care facility, or therapeutic radiological center which has care of or has diagnosed cancer or a central nervous system tumor for a non-hospitalized patient, and each physician who has care of or has diagnosed cancer or a central nervous system tumor for a non-hospitalized patient not otherwise reported shall:

- (i) 1. Submit a cancer report to the Secretary, on the form that the Secretary provides or in a computerized file;”

E. Maryland regulations regarding cancer reporting and data release:

COMAR 10.14.01.02 B(3), states:

““Cancer report”” means a one-time abstract from one or more of the following documents maintained by a reporting facility, nursing facility, assisted living program, or general hospice care program of each new case of reportable human cancer or CNS [central nervous system] tumor diagnosed or treated, and any other case of reportable human cancer or CNS tumor initially diagnosed or treated for time periods as designated by the Secretary:”

COMAR 10.14.01.06, states:

“A. A reporting facility shall submit a:

- (1) Cancer report to the Secretary in a computerized file containing standard information required by the Secretary;
- (2) Computerized file not less than quarterly; and

(3) Completed report of any new individual case of a reportable human cancer or reportable human CNS tumor not later than 6 months after diagnosis or treatment.

B. A nursing facility, an assisted living program, or general hospice care program shall submit a cancer report containing information that is under the control of the facility to the Secretary if the Secretary requests a cancer report on a patient who has been a resident of the nursing facility, assisted living program, or general hospice care program.”

COMAR 10.14.01.07, states, in part:

“A. Information obtained under this chapter is not a medical record under Health-General Article, §4-301, Annotated Code of Maryland, but is subject to the confidentiality requirements of Health-General Article, §§4-101—4-103, Annotated Code of Maryland.

B. The Secretary may release confidential data to:

(1) An institution or individual researcher for medical, epidemiological, health care, or other cancer-related or CNS tumor-related research approved by the Secretary and the Department's IRB in order to further the cancer control goals of the State set forth in Regulation .04 of this chapter;”

F. Confidentiality of MCR information and cancer cluster investigations:

The MCR regards all abstract records reported to the MCR as confidential. Data are secured from unauthorized access or disclosure. The MCR and its data management vendor manage and disclose information in accordance with Md. Ann. Health-General Art., §§4-102, 18-203, and 18-204 and COMAR 10.14.01 Cancer Registry. The MCR uses “cell suppression,” or deleting data from cells in tables to be released that contain data on one to five individuals to safeguard against the unintentional identification of individuals. Guidelines are detailed in Section 6.2 Release of Confidential Cancer Data in the Data Use Manual and Procedures, http://phpa.dhmh.maryland.gov/cancer/SiteAssets/SitePages/mcr_data/MCR%20DataUse%20Manual%20and%20Procedures%20102012.pdf.

Note that the MCR restricts release of confidential data under the provisions of COMAR 10.14.01.07. The Secretary or the Secretary’s designee, the DHMH-IRB, and the researcher’s own IRB must all approve the release of confidential data, and a Data Release Agreement with the MCR must be signed prior to such a release.

DHMH and local health departments (LHDs) will not share information with the person reporting a potential cluster or to the public for information collected by or reported to the MCR, including: 1) whether the data on an individual's tumor is or is not contained within the MCR; or 2) whether cancer cases reported by relatives, neighbors, providers or others are contained within the MCR. Similarly, maps that indicate the address at diagnosis of cancer cases are considered confidential because they may lead to identification of individuals.

G. Environmental and occupational disease reporting:

The reporting form for environmental and occupational disease reporting is available here: <http://eh.dhmh.md.gov/report/Occupational%20Reporting%20Form%20MD%20v1.pdf>.

This form states:

"In accordance with Maryland Code, the following conditions must be reported to the Department of Health and Mental Hygiene: (1) Pesticide-related exposures and illness; and (2) occupational illnesses."

For Work-Related Disease Outbreaks, this form states:

"Report any work-related disease outbreak/cluster, regardless of whether or not the disease is included among the reportable conditions listed above. A work-related disease outbreak is the occurrence of any illness in excess of normal expectation among workers at the same place of employment. Such outbreaks may be caused by exposures to a physical, biological or chemical hazard(s) in the workplace."

Environmental health resources for the public, consumers, and businesses in Maryland, <http://phpa.dhmh.maryland.gov/SitePages/environmental.aspx>.

H. Environmental Justice and Sustainable Communities

The Commission on Environmental Justice and Sustainable Communities (the Commission) was established by Executive Order on January 1, 2001 and is now statutorily codified under §1-701 of the Environment Article of the Md. Ann. Code. The Commission examines environmental justice and community sustainability issues that may be associated with creating healthy, safe, economically vibrant, environmentally sound communities for all Marylanders in a manner that allows for democratic processes and community involvement. Maryland's approach to environmental justice is consistent with the approach advocated by the United States Environmental Protection Agency (EPA). The Commission meets monthly.⁸

⁸ "What is Environmental Justice?" MDE, January 2014, <http://www.mde.maryland.gov/programs/CrossMedia/EnvironmentalJustice/WhatisEnvironmentalJustice/Pages/Programs/MultimediaPrograms/Environmental_Justice/ej_intro/index.aspx>.

V. Cancer and Cancer Clusters – Current Investigation and Communication

A. Cancer Reporting to the MCR and Data Available in Maryland

Maryland statute and regulations require reporting of tumors that are invasive cancer, in situ cancer, and benign brain or central nervous system tumors to the MCR within 6 months of diagnosis. Basal cell and squamous cancers of the skin are not reportable to the MCR. http://phpa.dhmh.maryland.gov/cancer/SitePages/mcr_home.aspx.

Through data exchange agreements with 12 states (Delaware, Pennsylvania, Virginia, West Virginia, Alabama, Florida, Georgia, New Jersey, New York, North Carolina, South Carolina, and Texas) and the District of Columbia, the MCR receives information on Maryland residents diagnosed or treated for reportable tumors diagnosed in these out-of-state jurisdictions. Maryland residents who are both diagnosed and treated outside of Maryland and outside of these 12 jurisdictions and the District of Columbia are not captured in the MCR database.

The MCR maintains data on required data elements from reported tumors in a computer-based cancer incidence data system maintained under the direction of DHMH. The MCR has data on the number of tumors reported with date of diagnosis in 1992 through the present. Because reports are not required until 6 months after diagnosis, the data from a diagnosis year is finalized, quality assured, and available approximately 14 months after the end of the diagnosis year (e.g., cases diagnosed January 1, 2011 through December 31, 2011 are in the final dataset available for analysis and release in March 2013, 14 to 26 months after date of diagnosis).

B. Current Maryland Procedures Used by State Agencies to Address Cancer Concerns

To respond to and investigate reports of potential cancer clusters:

The current DHMH instructions for responding to and investigating reports of cancer clusters are outlined in “Guidelines for the Management of Inquiries Related to Cancer Concerns or suspected Cancer Clusters, January 2010” (Maryland’s Guidelines) (Appendix D). This guideline was developed using CDC’s Guidelines for Investigating Clusters of Health Events published in 1990 and the cumulative experience of other state health departments.⁹ It gives general instructions on how Maryland responds to public cancer concerns and provides the State and local health agency roles. The document has been shared with each LHD in Maryland and with MDE.

Maryland’s Guidelines include a multistep process in response to cancer cluster concerns that proceeds sequentially based on the information collected and professional judgment, including: 1) **initial information collection**, including the number of cases, the types of cancers, the dates of diagnosis and ages of cases at diagnosis, the location of residence at the time of diagnosis, the source of potential exposure to carcinogen(s) for the cases, the occupation and worksite if a potential occupational cluster; 2) **preliminary investigation**,

⁹ “Guidelines for investigating clusters of health events,” *MMWR*, 39(1990):1-23, *CDC*, January 2014, <<http://www.cdc.gov/mmwr/preview/mmwrhtml/00001797.htm>>.

including some or all of the following: confirmation of cases and their diagnoses in the MCR, determining the number of cases in the MCR reported for that geographic area, often by age, by type of cancer, by year(s) of diagnosis, etc.; and 3) **further investigation**, including the determination of whether the number of cases for the cancer type is above expected for the geographic area compared to the county and Maryland as a whole. Additional steps of a major feasibility study and etiologic investigation are planned if a true cluster is possible given results from the first three steps in the evaluation.

"Questions and Answers about Cancer Clusters," basic information for the public is posted on the DHMH MCR web site, <http://phpa.dhmh.maryland.gov/cancer/Documents/Questions%20and%20Answers%20About%20Cancer%20Clusters.pdf>.

To report on cancer cluster investigations:

DHMH's Environmental Health Bureau (EHB) and the MCR maintain a log of inquiries related to cancer occurrences, potential clusters, and/or exposures thought to be associated with cancer risk. These requests come from citizens, LHDs, and other State agencies (particularly MDE). The outcome of the investigation is provided to the person/entity reporting a concern, either by telephone or in writing, from DHMH staff and/or LHD staff, typically preceded by consultations between MDE, local health and environmental health authorities, and DHMH. Following Maryland's Guidelines, which call for the professional judgment of Maryland staff at each step in the investigation of the reported situation, a community meeting may be held to convey the information found.

DHMH does not currently summarize or publicize reported cancer concerns/clusters or the responses/investigations beyond feedback provided to the person/entity reporting the concern.

To maintain confidentiality during investigations and during the reporting of investigations:

The DHMH and LHD team investigating a report of a cancer cluster discloses information consistent with the MCR's confidentiality policy. They will not share information with the person reporting a potential cluster or to the public for information collected by or reported to the MCR, including whether: 1) the data on an individual's tumor is or is not contained within the MCR; or 2) cancer cases reported by relatives, neighbors, providers or others are contained within the MCR. Similarly, maps that indicate the address at diagnosis of cancer cases are considered confidential because they may lead to identification of individuals.

Information that has been reported publicly by the media or in meetings or correspondence by community groups, and is therefore in the public domain, is generally not disclosed again (secondary disclosure) in the health department final report or in public meetings since the information may disclose identities, may be anecdotal, or may not be confirmed by investigators.

To identify potential cancer clusters:

No State agencies in Maryland currently have procedures to prospectively search for and identify potential cancer clusters in the state. Annually, the DHMH Center for Cancer Prevention and Control (CCPC) calculates rates of cancer by cancer type and by jurisdiction, gender, and race. These rates are assessed by reviewing historical trends. Sub-county geographic area rates are not calculated routinely, but have been calculated in specific investigations.

To identify potential environmental causes of cancer and to prevent exposure:

MDE's regulations, programs, and efforts are focused on protection of public health and the environment. Prevention of exposure to cancer-causing hazards is integrated into many MDE functions. Environmental monitoring related to MDE's regulatory and non-regulatory activities, coupled with public health communication and enforcement of State and federal requirements, can help identify and prevent environmental contributions to cancer.

MDE regulates Maryland military installations under its array of existing laws, rules, and policies that address potential environmental impacts associated with military activity. To help Maryland installations understand and keep pace with State regulatory requirements as well as to encourage voluntary pollution prevention efforts, MDE meets regularly with environmental managers from U.S. Department of Defense/Joint Services under an intergovernmental partnership agreement that was executed in 2002.

C. Number of Cancer Cluster Investigations and Current Resources for Investigation

Since 2009, there have been 57 cancer clusters or concerns reported to DHMH and handled according to Maryland's Guidelines (Appendix D):

- 39 were handled by discussion with the reporters after initial information collection and often a preliminary investigation;
- 12 required analysis of additional cancer registry data and/or local or state environmental input;
- Four were reports of workplace concerns that were addressed by discussion with the people reporting and with LHDs. Investigation may have included interviews and visual environmental assessment of the worksites; none could be investigated using MCR data because worksite location is not a field captured for cancer cases registered in the MCR database;
- Two were more in depth investigations where standardized incidence ratios were calculated based on MCR data and information was presented at community meetings; and
- None of the reported clusters or concerns was found to be a cluster of a specific type of cancer; none was linked to specific environmental factors (see Definitions). Thus, none of the reported potential cancer clusters met the definition of a cancer cluster.

Current resources for investigation include staff of DHMH EHB and CCPC's MCR; MDE; and staff of Maryland's 24 LHDs and environmental health units. These investigations involve staff with medical, epidemiologic, and/or environmental health expertise. None of these staff are solely dedicated to investigating reported cancer clusters or concerns, but all

participate when issues arise. All have roles specified in Maryland's Guidelines (Appendix D). Reporting to or requesting the involvement of Maryland academic medical centers or federal agencies is not part of routine investigation procedures; however, if a confirmed cancer cluster was identified, assistance from academic medical centers, CDC, and/or the National Institutes of Health (NIH) is possible. Such assistance may require IRB approval, or a contractual agreement in the case of the academic medical centers.

D. Communication Among State Agencies and Among State and Federal Agencies Regarding Investigation of, Research about, and Identification of Cancer Clusters

There is communication at the time of the report of a cancer concern, and throughout the initial response between DHMH units and the LHD of the jurisdiction from which the concern was reported. MDE is informed if the investigation proceeds to the second phase of initial evaluation, or if the initial report specifies an environmental concern.

DHMH only reports cancer cluster issues to federal agencies (CDC, NIH, EPA, NIOSH, etc.) when DHMH or MDE decides to request additional information, assistance with statistical methods, or additional investigation staff. On several occasions, MDE and DHMH (as well as local jurisdictions or individuals) have contacted the Agency for Toxic Substances and Disease Registry (ATSDR), which is a part of the CDC, regarding potential cancer clusters.

VI. Research on Potential Cancer Clusters

Academic medical institutional research is focused on molecular aspects of cancer, cancer mechanisms (including carcinogens and genetic susceptibility), and cancer diagnosis and treatment. It has not focused on cancer cluster investigations directly, such as when situations are reported to public health agencies by the public seeking investigation and answers. That responsive role has fallen to public health agencies. More extensive cancer cluster investigations by academic medical institutions may not be possible without additional funding and without solving certain confidentiality issues.

University colleagues share their expertise with DHMH and MDE in situations such as participating on advisory committees or on this Workgroup, or fulfilling requests for information when asked. In their reports to the Workgroup the academic institutions did not address regular reporting to, or communication with, federal agencies regarding cancer clusters.

It should be noted that while the Workgroup heard from two academic institutions (Johns Hopkins University and the University of Maryland) about their work related to the Workgroup's charge, there are other academic institutions within Maryland that may also have research and practice related to cancer and potential cancer clusters.

A. Research at the University of Maryland School of Medicine (UMSOM) and University of Maryland Cancer Epidemiology Alliance (UMCEA) with University of Maryland College Park (UMCP) Faculty

UMSOM conducts basic cancer research, translational research, and population-based research:

- Basic cancer research: Examining gene expression during early stages of cancer development possibly to use as a biomarker of cancer risk or onset of cancer;
- Translational research: Taking the results of basic research and implementing treatment and programs for better cancer prevention and control; and
- Population-based research: For primary cancer prevention, early detection, and community education.

UMSOM's Department of Epidemiology and Public Health (DEPH) faculty conduct epidemiological research on cancer risk factors to determine how the environment, behavior, and genetics, alone and in combination, can influence cancer risk. UMSOM DEPH's Division of Cancer Epidemiology conducts research that includes the impact of nutrition and metabolism, infection and inflammation, endocrinology, and genetics on cancer development. Cancers of primary research interest in this group include breast, skin, lymphomas, colon, head and neck, and cervical cancers. Many projects are focused on genetic differences that can directly alter risk, or may indirectly affect susceptibility due to gene/environment interactions. Other researchers have used MCR data to examine disparities in breast cancer treatment.

The UMSOM DEPH's Division of Cancer Epidemiology has established a University of Maryland Cancer Epidemiology Alliance (UMCEA) with faculty in the UMCP's School of Public Health to promote collaboration in research and education in cancer epidemiology and population research on both UM campuses. UMCEA's research:

- Includes human behavior research which can help in understanding cancer risk factors, and in understanding how best to establish working relationships with community groups; and
- Is conducted on the genetics of susceptibility to carcinogens. In particular, faculty are examining associations between environmental factors and the development of specific cancers. Primary research areas related to cancer risk are shown in Appendix E, and include genomic studies (genetic susceptibility) and gene/environment interactions; diet, nutrition and metabolism; endocrinology; inflammation and infections; viruses; environmental chemicals (such as hazardous drugs, solvents, and pesticides); and effects of early life-stage exposures on risk.

The UMSOM Department of Pathology, with the National Cancer Institute (NCI) Laboratory of Human Carcinogenesis, has for 30 years conducted a case-control study for cancer in the State of Maryland, focusing on lung, prostate, liver and pancreatic cancers.

B. Research at the Johns Hopkins University

Johns Hopkins Medical Institutions faculty conduct research similar to the topics listed above for UMSOM. In the past, disease clusters of suspected environmental etiology have been investigated by Johns Hopkins faculty upon request of State or local entities. Preliminary investigations associating cancer incidence and the environment have been done with pro bono faculty and student assistance after researchers apply for and are granted IRB approval access to appropriate data.

VII. Findings of the Workgroup on Cancer Clusters and Environmental Causes of Cancer

The following findings are based on presentations to the Workgroup and Workgroup discussions. For a list of presentations, see Appendix B. The order in which these findings appear does not indicate their relative importance or priority.

Finding 1: Cancer is not one disease but a group of diseases characterized by uncontrolled growth and spread of abnormal cells. Cancer as a whole is relatively common, but specific types of cancer range greatly in their incidence and prevalence. Generally, with the exception of childhood cancers, age is the strongest risk factor for adult forms of cancer.

1. All cancers involve the malfunction of genes that control cell growth and division, but most of these malfunctions are due to mutations (alterations in the DNA) that are accumulated in cells (somatic mutations) over the life of the person rather than inherited genetic changes. About 5% to 10% of all cancers occur due to a strong inherited genetic factor that confers a high risk of developing one or more specific types of cancer. This inherited genetic susceptibility to cancer is distinguished from the more common somatic mutations that may occur and accumulate during one's lifetime. Genetic damage resulting from these accumulated alterations in DNA may result from internal factors, such as hormones, the metabolism of nutrients within cells, or poor repair of regularly occurring damaged DNA, or external factors, such as tobacco or excessive exposure to chemicals, sunlight, or ionizing radiation.¹⁰
2. Cancer, considering all types, is common but the rates of individual cancer sites vary greatly. The most common types of cancer include lung, colorectal, prostate, and breast cancer. The underlying risk factors for cancer vary by the specific type of cancer. One in 2 men and 1 in 3 women in the U.S. will be diagnosed with some type of invasive cancer in their lifetime (excluding squamous and basal cell skin cancer).¹¹
3. Age is the strongest risk factor for the majority of cancer types. Seventy-seven percent of all cancers are diagnosed in people age 55 years or older.¹² Although cancer rates in Maryland and the U.S. are falling slowly, as the population ages, the number of people with cancer increases because there are more older adults. Similarly, as the rates of heart disease and stroke decline, proportionally, the number of people affected with cancer and the number of deaths from cancer relative to other causes has been increasing.¹³

Finding 2: Currently in Maryland, cancer clusters or cancer concerns are raised by one or more residents and reported to the State or LHDs; proactive identification of cancer clusters is not done.

Finding 3: The Maryland "Guidelines for the Management of Inquiries Related to Cancer Concerns or Suspected Cancer Clusters, January 2010" (Appendix D) are consistent with CDC

¹⁰ "What is Cancer?" 7 March 2014, NCI at the NIH, January 2014,

<<http://www.cancer.gov/cancertopics/cancerlibrary/what-is-cancer>>.

¹¹ "Cancer Facts & Figures, 2013," 2013, American Cancer Society, January 2014,

<<http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-036845.pdf>>.

¹² Surveillance, Epidemiology, and End Results: SEER 18 2006-2010, All Races, Both Sexes. January 2014, <<http://seer.cancer.gov/>>.

¹³ George Johnson, "Why everyone seems to have cancer," 5 January 2014, New York Times, January 2014, <http://www.nytimes.com/2014/01/05/sunday-review/why-everyone-seems-to-have-cancer.html?_r=0>.

Guidelines for cancer cluster investigation published in 1990 and other state guidelines.¹⁴ New guidelines from CDC and the Council of State and Territorial Epidemiologists were published in September 2013; updates and changes to Maryland's Guidelines have not yet been made but are anticipated.¹⁵

Finding 4: Federal agencies (e.g., CDC, ATSDR, NCI/NIH) are not routinely involved in cancer cluster investigations when reports are received by the states. Neither is there routine communication of cancer cluster reports by Maryland to any federal agency.

Finding 5: The public and public health professionals may differ in their perception of: 1) what constitutes a "cancer cluster"; and 2) the ability of an "investigation" to identify whether there is a cluster and if so, the possible cause of the cluster. The public often reports concerns about a number of cancer cases diagnosed among residents of a local neighborhood or of people they believe may have had a common exposure to carcinogens from an environmental source.

The Workgroup heard from the public, experts in cancer epidemiology, Frederick County and Montgomery County health officials, and a Delaware cancer epidemiologist about cancer concerns reported by the public. Experts pointed to the many potential difficulties in associating reported cancer cases and cancer clusters with environmental factors, difficulties that the person who reports the cluster is often unaware of. Difficulties include:

- Cancer is common and more common with increasing age (see Finding 1), thus communities with an aging population would be expected to have a higher number of cancer cases;
- The term "cancer" refers to a multitude of specific types of cancer with different rates of occurrence and different contributing factors. A "cancer cluster" is often reported when the person believes that the number of cancer cases is greater than what the person expects for the time and location. These reports often contain a set of different cancer types, each of which has different and unrelated contributing factors and different expected rates of occurrence;
- The causes of cancer are multifactorial and vary by type of cancer, with interaction among non-modifiable risk factors (e.g., genetic susceptibility, age, gender), modifiable personal risk factors (e.g., smoking, alcohol use, infections by carcinogenic agents, etc.), occupational exposure to carcinogens, and environmental factors (e.g., in air, water, soil);
- "Exposure" to a carcinogen does not necessarily imply increased risk of cancer for an individual; the individual's risk of cancer due to the exposure is associated with the internal dose of that exposure, the individual's susceptibility, the concentration of the carcinogen, the route and length of the exposure, and the latent time interval (latency) between exposure to carcinogen(s), and the development and diagnosis of cancer, which is often measured in decades. During this latency period, people have often moved away from potential exposures so that their "address at diagnosis" in the MCR is not associated with any site of potential exposure years before;
- Identifying and subsequently locating individuals who lived in an area years before;
- Ambient environmental monitoring (air, water, soil) for all potential carcinogens;

¹⁴ *Id* fn 9.

¹⁵ *Id* fn 1.

- Ambient levels of environmental carcinogens do not necessarily reflect personal exposure or internalized dose of the exposure;
- The MCR database does not contain information about potentially important cancer risk factors, such as previous place(s) of residence and known personal risk factors (e.g., smoking history), and it has insufficient reporting of occupation and industry of employment and occupational exposures; and
- Prospectively identifying either actual or potential cancer clusters, or the risk factors and exposures that might explain an actual cluster, high potential of “false positive” identification of clusters as was seen in Delaware, limited resources of the public health agencies, defining the time and place boundaries of an investigation, limitations of current epidemiologic methods for small area analysis, and lack of specific environmental monitoring for many relevant exposures.

Finding 6: Exposure prevention efforts could benefit from the availability of robust methods to assess cumulative exposure of vulnerable populations. The Workgroup heard that there are substantial methodologic and regulatory challenges to considering cumulative exposures, although these cumulative exposures may be very important.

Finding 7: There have been few actual cancer clusters identified nationally, despite hundreds of investigations, and it is rare to identify any clusters associated with an environmental exposure or cause.^{16,17,18,19} In Maryland in at least the past seven years, no confirmed cancer clusters have been identified among those reported to DHMH.

The Workgroup heard from several experts, including Judy LaKind, who pointed out that:

- A cancer cluster is a greater-than-expected number of cancer cases that occurs within a group of people in a geographic area over a period of time.
- After conducting a systematic review of state investigations in the U.S. from 1990-2011, only 72 of the 567 reported clusters were confirmed cancer clusters. Only three of the 72 confirmed clusters were associated with an environmental exposure, and only one of the 72 had an established cause.
- Current extensive nation-wide efforts to find environmental causes for community cancer cluster concerns have not been successful.
- Other means of investigating such clusters in the future may include:
 - Utilizing automated “data mining” algorithms to identify space-time clusters of cancers in cancer registries;
 - Reconstructing residential history among cancer cases;
 - Improving utilization of electronic data sources; and
 - Linking cancer cases with certain infections.

¹⁶ *Id* fn 2.

¹⁷ *Id* fn 3.

¹⁸ MJ Thun and T Sinks, “Understanding Cancer Clusters,” *CA Cancer J Clin*, 54(2004):273-80, [PubMed](http://www.ncbi.nlm.nih.gov/pubmed/15371285), January 2014, <<http://www.ncbi.nlm.nih.gov/pubmed/15371285>>.

¹⁹ Nadia Juzych et al., “Adequacy of State Capacity to address noncommunicable disease clusters in the era of environmental public health tracking,” *Am J Public Health*, 97S(2007):163-9, [PMC](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1854996/), January 2014, <<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1854996/>>.

Finding 8: Creating opportunities for people with cancer to tell their "stories" can be valuable for individuals and for communities concerned about possible environmental exposure and cancer. However, this is not necessarily the exclusive or primary role of the public health investigation; it may be fulfilled by community meetings or other forums.

Finding 9: Some improvements in timeliness, completeness, accuracy, and collection of additional data on each case reported in the MCR may be possible, but would require a considerable investment of time and money. More rapid reporting might improve the MCR's ability to confirm the diagnosis of a reported case of cancer.

The MCR currently follows the standards of the National Program for Cancer Registries (NPCR) and the North American Association of Central Cancer Registries (NAACCR) and has achieved Gold status (the highest status) for accuracy, completeness, and timeliness of reporting. Rapid case ascertainment (so that data are available for analysis sooner after diagnosis) might require an increase in resources and financial support for both the MCR and the hospital-based cancer registrar reporters. If the American College of Surgeons requires rapid ascertainment for hospital accreditation, this may be more feasible. Acquiring and entering additional risk information in the MCR database on each case reported (e.g., risks such as tobacco use, residential addresses over time, occupation, site(s) of work, past medical procedures, etc.) would be difficult or impossible, but if it could be accomplished, additional risk factor information could help in investigations. The feasibility of adding this information for selected cases could be explored, especially collecting additional data on cases that may be part of a cluster.

Finding 10: There are opportunities for improved State communication with Federal agencies when clusters are reported or identified. Such communication is not required and does not currently occur in a systematic fashion. There is occasional communication with agencies such as CDC, ATSDR, EPA, and NIH/NCI, but these communications are generally related to specific technical questions.

Finding 11: There are opportunities to provide additional information to the public regarding cancer rates, cluster reports, and potential environmental contributions to cancer at the State, county, or sub-county levels through annual reports and other information channels such as online data access and existing web sites. This information might help to alleviate public concerns about cancer clusters or to increase public satisfaction with the investigation of such concerns. Additional funding could enhance the development and dissemination of additional information.

Finding 12: The Workgroup looked at the experience of other states. Delaware Health and Human Services, Division of Public Health has produced cancer incidence rates and maps for certain cancers at the Census Tract level for their state.^{20,21} The Workgroup heard that as a

²⁰ "On the Map: Information on Delaware's Cancer Rates by Census Tract," Delaware Health and Social Services Division of Public Health, January 2014, <<http://dhss.delaware.gov/dph/files/onthemap2008.pdf>>.

²¹ "Secondary Analysis of Census Tracts with Consistently-Elevated All-Site Cancer Rates in Delaware, 2001-2005, 2002-2006, 2003-2007, 2004-2008 and 2005-2009," April 2013, Delaware Health and Social Services Division of Public Health, January 2014,

result, Delaware evaluated census tracts with relatively high rates, but did not identify any actual clusters related to environmental exposures. New York has mapped environmental facilities and cancer rates.²²

Finding 13: Research at academic medical institutions is principally focused on molecular aspects of cancer, cancer mechanisms (including carcinogens and genetic susceptibility), and cancer diagnosis and treatment. Research may address the methods applied to cancer cluster investigation. Research has not focused on investigating cancer clusters per se, such as when situations are reported by the public seeking investigation and answers.

Finding 14: Opportunities exist to enhance interaction between public health agencies and academic medical institutions regarding environmental contributions to cancer and ways to address public concerns about cancer clusters.

Finding 15: Opportunities exist to educate the public about cancer (including recognition of cancer as a group of distinct diseases), cancer prevention (including genetic and environmental risk factors; how to identify exposures and reduce them), cancer clusters, and cancer screening.

Finding 16: The Toxic Substances Control Act (TSCA) of 1976 provides the EPA with authority to require reporting, record-keeping and testing requirements, and to enact restrictions relating to chemical substances and/or mixtures.²³ Certain substances are generally excluded from TSCA, including food, drugs, cosmetics, and pesticides which are subject to other regulation. TSCA addresses the production, importation, use, and disposal of specific chemicals including polychlorinated biphenyls (PCBs), asbestos, radon, and lead-based paint. There are current efforts at the federal level to update and reform TSCA and strengthen chemicals management. MDE is following discussions about current TSCA reform efforts and is considering potential implications for chemicals management in Maryland.

Finding 17: Some states are pursuing comprehensive approaches to chemicals management and exposure prevention. Examples of these efforts include identification and prioritization of chemicals of concern, consideration of exposures through chemicals in consumer products, and promotion of safer product design and safer alternatives to toxic chemicals. Some states are using the Interstate Chemicals Clearinghouse (IC2) an association of state, local, and tribal governments that promotes a clean environment, healthy communities, and a vital economy through the development and use of safer chemicals and products.²⁴ Eleven states have agencies that have joined the IC2, although Maryland has not.

Finding 18: The extent of knowledge about drinking water quality (including contaminants that can increase cancer risk) in Maryland is significantly greater for public water systems than for private wells. For public water systems, routine monitoring of water quality is overseen and

<http://dhss.delaware.gov/dph/dpc/files/2ndaryanalysis_consistencyhigh2009.pdf>.

²² “Environmental Facilities and Cancer Mapping,” January 2013, New York State Department of Health, January 2014, <http://www.health.ny.gov/statistics/cancer/environmental_facilities/mapping/>.

²³ “Overview: Toxic Substances Control Act,” 26 March 2014, EPA, January 2014, <<http://www.epa.gov/enviro/facts/tsca/>>.

²⁴ “What is Interstate Chemical Clearinghouse (IC2)?” 26 July 2013, Northeast Waste Management Officials’ Association, January 2014, <<http://www.newmoa.org/prevention/ic2/about/factsheet.cfm>>.

enforced by MDE, which consistently operates within the federal Safe Drinking Water Act. For private wells, routine monitoring of water quality is not required or regulated.

Regarding public concerns about drinking water and the risks of cancer, public water systems are regulated by MDE under a formal delegation of authority from the EPA, which provides stringent oversight of the State's regulatory program. Public water supplies are regularly tested and monitored for more than 100 contaminants that could pose acute or chronic health risks. If any one of those contaminants is detected above an acceptable level, the public is immediately notified. In addition, the test results are reported annually to consumers and MDE posts the results on the web site, affording consumers access to information about the quality of their publicly-supplied drinking water.

Regarding the potential presence of cancer-causing substances in individual wells, MDE works with LHDs and other agencies to identify areas that may be subject to contamination, based on geology, aquifer data, and/or studies. When areas of contaminated individual wells are identified, federal, state, and local agencies work together to provide short-term and long-term treatment or alternative water sources. MDE has capital programs that can be used to connect affected homes to public water supplies, where appropriate and available. With additional resources, MDE would support more outreach and education to homeowners to ensure that best practices are used to prevent groundwater contamination and to test periodically for common contaminants.

Finding 19: MDE participates alone or in collaboration with DHMH, LHDs, and other agencies to respond to concerns or reports involving environmental hazards. Potential health risks, including cancer risks, are routinely used to guide decision making during these responses. The use of either regulatory measures or non-regulatory measures, or a combination thereof, depends on the specific scenario that prompted the response.

VIII. Recommendations of the Workgroup on Cancer Clusters and Environmental Causes of Cancer

Note: The following recommendations were not prioritized by the Workgroup. The order in which they appear does not indicate their relative importance or priority.

A. To identify, investigate, and assess potential cancer clusters when the public reports cancer clusters or cancer occurrences of concern:

Recommendation A1: DHMH should update and enhance its “Guidelines for the Management of Inquiries Related to Cancer Concerns or suspected Cancer Clusters, January 2010” by incorporating: 1) the 2013 “Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists,” 2) alternative approaches to investigation, and 3) the following suggestions of the Workgroup:

- Publicize information on how to report cancer concerns/suspected clusters via web sites or by telephone to DHMH or to LHDs. Add these web sites or telephone numbers for reporting to appropriate DHMH, MDE, and LHD web pages. Draft sample web pages or give links to DHMH web sites for distribution and posting to LHD web sites.
- Provide in lay language the steps of an investigation to be available in on-line and printed versions.
- Adhere to timelines for investigation and reporting that are stated in Maryland’s Guidelines.
- Specify how data are handled and the guidelines governing the confidentiality of individual reports and of investigation information.
- When a further investigation is indicated, carry out a needs assessment, formulate a protocol, and specify needed resources for the investigation. This should additionally specify the information to be gathered on cancer cases (including but not limited to confirmation of diagnoses; collection of personal exposure histories including lifestyle factors, residences, occupational histories, medical histories, etc.); the selection of and information regarding comparison populations; information to be collected on the environment (geology, ground and surface water sources, etc.); potential blood, tissue or other human samples to be collected and correspondingly the potential need for IRB approval; and the agencies/consultants to be involved and funding sources.
- Have an online training program for LHDs who will receive reports from the public. Include specific information about who should receive reports and what actions they should take.

Recommendation A2: DHMH should more clearly identify the criteria and process it will use to determine when and how far to proceed with investigating a report of a cancer cluster received from the public or a healthcare provider.

- Specify in Maryland’s Guidelines the role that the judgment of public health professionals plays in proceeding to the next step in the investigation.

- State who is responsible for making the decisions (e.g., local/state/multiple agencies or single individuals).
- Explicitly specify how the decision will be made whether to pursue a further investigation or not and the specific factors and evidence (e.g., number of cases, types of cancer, statistical analyses) that will be used to make this decision.
- Specify under what circumstances situations either will be reported to the CDC or will lead to a request for additional assistance in an investigation.
- Specify that investigations necessarily will be prioritized based on factors such as: nature of risk, whether there is ongoing risk, whether there is a unique cancer type reported, age of onset of cancer cases, unique exposure situations, and available resources and clarify how these factors will be weighed.

Recommendation A3: DHMH MCR should determine the feasibility of improving the data on each reportable tumor in the database or on a subset of cases of environmental concern (sentinel cases) to include more exposure information such as past residential addresses, and occupation information.

- Determine the feasibility of enhancing MCR data (every case reported or a subset of cases of interest) by linking the MCR reports with alternate sources of data, such as State Health Information Exchange data to:
 - Facilitate more rapid reporting of cases; and/or
 - Potentially obtain more complete history of residence, tobacco and alcohol use, certain past infections, and occupational exposure on all or a subset of cases in the MCR database if this information exists in the electronic health records.

Recommendation A4: Have an advisory committee of the DHMH CCPC review DHMH cancer cluster responses to ensure consistency and potentially to improve the investigation methods and processes.

B. To use existing data to identify cancer clusters or cancer occurrences of concern:

Recommendation B1: Collaborate with academic medical institutions and Federal agencies on approaches to the identification, evaluation, and investigation of cancer clusters or cancers of concern that are identified by DHMH.

Recommendation B2: DHMH should convene a group* to:

- Determine what sentinel events could be actively surveyed using MCR data;
- Explore and suggest investigation approaches regarding: 1) potential exposures in the state to environmental factors that are known to cause cancer (particularly carcinogenic chemicals or ionizing radiation), and 2) geographic areas of concern for potential exposures, or 3) increased observed cancer rates; and
- Explore analytic methods and criteria to determine whether there are geographic areas in Maryland with disparities in exposure or potential exposure to environmental hazards that are known or suspected to cause cancer (particularly carcinogenic chemicals or ionizing

radiation). Where such areas are found, explore whether an assessment of risk associated with the exposure should be undertaken.

*The Workgroup agreed that, given the Workgroup's scope, time limitations, and the need for input from others with different expertise, these tasks are better suited for another group limited to only these specific tasks.

C. To educate the public about exposure to and risk from environmental factors that are known to cause cancer; to prevent exposures:

Recommendation C1: With additional funding, the DHMH EHB and MDE should improve access to cancer data and environmental data by publishing maps of cancer rates that also include the capacity to show environmental information such as environmental monitoring data, or sites listed on the National Priority List or Toxic Release Inventory.

- DHMH should improve public health information regarding the distribution of rates of specific cancers at the county and sub-county geographic levels by making this information available at LHDs and online; DHMH and MDE should make available maps and tools concerning environmental data such as the Toxic Release Inventory or the National Priority List, which are of interest to the public in the context of cumulative exposures and cancer risk; and
- DHMH should have a web site that includes both professional and lay public versions of MCR data – and data (numbers and rates) should be made available in the smallest geographic area that can provide reliable statistics without breaching confidentiality. When appropriate, MCR data should be made available under IRB-approved protocols.
- Risk messages accompanying maps of cancer data should help users think about the interpretation of data, including concepts such as cumulative exposure and risk, and the difference between association and causation.

Recommendation C2: With additional funding, enhance the EHB web site to include public information regarding environmental factors that cause or contribute to cancer and prevention of cancer by reducing such exposures. This would include messages regarding exposures to modifiable environmental risk factors, such as indoor air and household exposures, tobacco and alcohol use, radon exposure, sunlight and artificial sources of ultraviolet light, and occupational carcinogens.

Recommendation C3: Maryland should expand efforts on prevention strategies aimed at reducing exposures to known carcinogens:

- Maryland should evaluate examples from other states that are pursuing a comprehensive approach to chemicals management and exposure prevention. Based on this evaluation and other considerations, Maryland should explore the feasibility of a comprehensive approach to chemicals management and exposure reduction through a combination of outreach and education, labeling, and stronger regulatory mechanisms.
- Maryland should encourage federal action to update and strengthen the Toxic Substances Control Act and/or otherwise strengthen chemicals management at the federal level.

- Maryland should consider using resources such as the IC2 to educate the public, and the potential value of joining IC2 as a part of a State strategy to reduce exposures and strengthen chemicals management.

Recommendation C4: Given public concerns about drinking water and the risk of cancer, MDE and DHMH should: 1) work together to increase public awareness of existing water supply testing requirements and other regulatory measures designed to ensure safe drinking water; and 2) consider whether changes to existing testing requirements for private wells are advisable.

D. To research potential cancer clusters:

Recommendation D1: Establish a mechanism for information sharing and collaboration among researchers, the DHMH MCR and EHB, MDE, and other public health programs in Maryland. In particular, create opportunities for regular exchange of information between researchers and public health and environmental agencies regarding public concerns and inquiries, environmental monitoring, and advances in understanding of cancer mechanisms. Entities should share research findings and/or cancer cluster investigation information, and should collaborate on approaches to public cancer concerns including methods of identification, investigation, and prevention.

E. To communicate to the public through annual reports:

Recommendation E1: The MCR Cancer Incidence and Mortality Report could include the number of cancer concerns reported to DHMH and the outcome of those reports. This report would be publicly available on DHMH web sites.

Recommendation E2: If DHMH and MDE develop a systematic approach to chemicals of concern as called for in Recommendation C3, the approach should include an annual public report on processes and findings.

F. Resources needed:

Recommendation F1: Maintain funding for cancer investigation and outreach-related activities in the DHMH EHB and MCR.

Recommendation F2: Increase funding to DHMH and MDE to implement the Workgroup's recommendations regarding enhanced health education messaging about cancer prevention, environmental carcinogens, and exposures of concern, and to enable additional collection, analysis, and/or presentation of data.

Appendix A: Members of the Workgroup on Cancer Clusters and Environmental Causes of Cancer

Name	Position	Organization	Meeting Attendance						
			7/23/13	8/20/13	9/10/13	9/30/13	10/21/13	11/15/13	12/5/13
Paul Bixenstine	MD Candidate	Johns Hopkins School of Medicine	x	x	x			x	x
Charnise Carter	Executive Director	Juice 4 Life, Inc.	x	x	x	x	x		x
Diane Dwyer, MD	Medical Director	DHMH Center for Cancer Prevention and Control	x	x	x	x	x	x	x
Ken Eidel*	Cool Cities Coordinator/Treasurer	Catoctin Group Sierra Club		x	x	x	x	x	x
Kira Eyring	Account Rep, Hospital Systems	American Cancer Society			x	x	x		
Cheryl Glenn	Delegate	Maryland House of Delegates							
Kathleen Griffith, PhD, MPH, CRNP	Assistant Professor	University of Maryland School of Nursing	x	x		x	x		
Kathy Helzlsouer, MD, MHS	Director	The Prevention and Research Center, Mercy Medical Center	x	x	x	x	x	x	
Norma Kanarek, MPH, PhD	Associate Professor	Johns Hopkins School of Public Health	x	x	x	x	x		
Jenny Levin*	State Advocate	Maryland Public Interest Research Group (PIRG)	x	x	x	x	x		
Julian Levy, Jr., MS	President	Levy Environmental Consulting, Ltd.	x	x	x		x	x	x
Courtney Lewis, MPH	Director	DHMH Center for Cancer Prevention and Control	x	x	x	x	x	x	x
Cathy McLain	COO	Cherry Hill Trust, Inc.	x						
Jed Miller, MD	Environmental Health Advisor	Maryland Department of the Environment	x	x	x	x	x	x	x
Clifford Mitchell, MS, MD, MPH	Director	DHMH Environmental Health Bureau	x	x	x	x	x	x	x
Anthony Muse, DMin	Senator	Maryland Senate	x	x	x	x		x	
Amir Sapkota, PhD	Assistant Professor/ Affiliate Faculty	University of Maryland	x		x	x			
Katherine Squibb, PhD, MS	Professor	University of Maryland, School of Medicine		x				x	

* Member represents rural areas in Maryland.

Appendix B: Workgroup Meeting Dates and Agenda Items

Meeting Date	Meeting Topics	Meeting Presenters	Title	Organization
July 23, 2013	Overview of the Workgroup's Purpose and Charge; Discussion of the Final Workgroup Report; Draft Public Comment Request	Courtney Lewis, MPH	Director	DHMH Center for Cancer Prevention and Control
	Review of Existing Guidelines for Cancer Cluster Investigations	Diane Dwyer, MD	Medical Director	DHMH Center for Cancer Prevention and Control
August 20, 2013	Cancer Cluster Investigations in Maryland	Diane Dwyer, MD	Medical Director	DHMH Center for Cancer Prevention and Control
	Frederick, MD Cancer Cluster Investigation Case Study	Barbara Brookmyer, MD, MPH	Health Officer	Frederick County, Maryland
	Frederick, MD Cancer Cluster Investigation Case Study	Beth Resnick, MPH	Director	Johns Hopkins Bloomberg School of Public Health
September 10, 2013	Framework for Cancer Clusters and Environmental Causes of Cancer	Diane Dwyer, MD	Medical Director	DHMH Center for Cancer Prevention and Control
	Poolesville, MD Cancer Cluster Investigation Case Study	Colleen Ryan-Smith, MPH	Epidemiologist	Montgomery County Department of Health and Human Services
	Cancer Clusters in the USA: What Do the Last 20 Years of State and Federal Investigations Tell Us?	Judy LaKind, PhD	President	LaKind Associates, LLC
September 30, 2013	Brief on Environmental Exposures around Fort Detrick Area B	John Bee, LSRP, PG	President	Tapash, LLC
	National Institutes of Health Role in Investigating Cancer Clusters	Deborah Winn, PhD	Deputy Director	Division of Cancer Control and Population Sciences, National Cancer Institute
	Proactive Identification of Areas with Increased Rates of Cancer	Judy Walrath, PhD	Epidemiologist	Delaware Division of Public Health
October 21, 2013	Managing Chemicals in Commerce - State Approaches	Kathy Kinsey	Deputy Secretary	Maryland Department of the Environment
	State Efforts to Manage Chemicals of Concern	Jenny Levin	Public Health Advocate	U.S. PIRG
November 15, 2013	Academic Research on Potential Cancer Clusters	Katherine Squibb, PhD, MS	Professor	University of Maryland School of Medicine
	Final Report Discussion; Workgroup Recommendations	Diane Dwyer, MD	Medical Director	DHMH Center for Cancer Prevention and Control
December 5, 2013	Review and Discuss Workgroup Recommendations	Diane Dwyer, MD	Medical Director	DHMH Center for Cancer Prevention and Control

Appendix C: Text of Request for Public Comment Posting

Department of Health and Mental Hygiene Workgroup on Cancer Clusters and Environmental Causes of Cancer

Request for Public Comment

The Department of Health and Mental Hygiene has convened a Workgroup on Cancer Clusters and Environmental Causes of Cancer, pursuant to Senate Bill 380. The current process that is used in Maryland to investigate suspected cancer clusters can be found at:

[http://phpa.dhmh.maryland.gov/cancer/Documents/homemos/Shared10/03/ccsc10-03 att guideline cancer cluster01082010.pdf](http://phpa.dhmh.maryland.gov/cancer/Documents/homemos/Shared10/03/ccsc10-03_att_guideline_cancer_cluster01082010.pdf)

The Department is seeking comments from the public, including individuals **who have knowledge of or have been involved with** a community cancer cluster investigation in Maryland, regarding the following questions:

1. Would you know who to contact if you were concerned about a suspected cancer cluster?*
2. Do you have comments on the current process used in Maryland to investigate suspected cancer clusters?
3. For individuals who have been impacted by a community cancer cluster investigation:
 - a. Were you satisfied with the availability of State and local health department staff during the cancer cluster investigation?
 - b. Were you satisfied with the communication that you received from State and local health department staff about:
 - i. the progress of the investigation, and
 - ii. the findings of the investigation?
 - c. Was the investigation conducted in a timely manner?
 - d. Were your concerns related to the suspected cancer cluster or investigation addressed to your satisfaction?
 - e. Did you feel well-informed about the investigation?
 - f. Do you have any suggestions for improvement in the cancer cluster investigation process, including follow-up?
 - g. Do you believe that current reporting of cancer cluster investigation findings is adequate? If not, how often, in what format, and to whom should investigation findings be reported?

*For information about cancer cluster reporting, visit:

http://phpa.dhmh.maryland.gov/cancer/Documents/mcr_combined_cancer_cluster.pdf

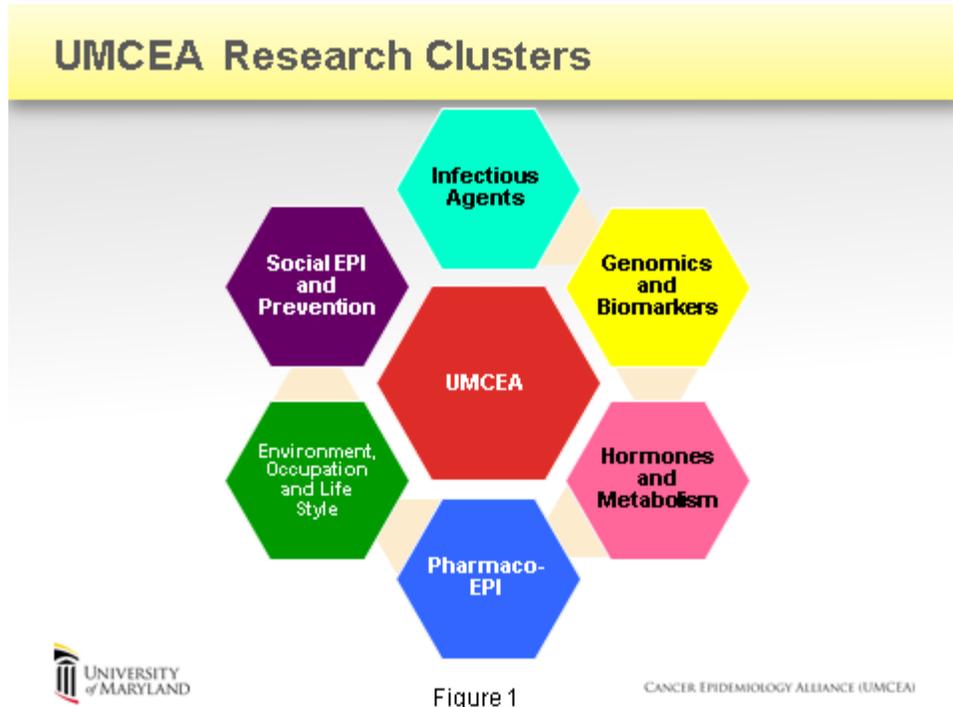
Please send your comments by **September 3, 2013** to:

meredith.truss@maryland.gov

Appendix D: Guidelines for the Management of Inquiries Related to Cancer Concerns or Suspected Cancer Clusters, January 2010

The current process that is used in Maryland to investigate suspected cancer clusters can be found at: [http://phpa.dhmh.maryland.gov/cancer/Documents/homemos/Shared10/03/ccsc10-03 att guideline cancer cluster01082010.pdf](http://phpa.dhmh.maryland.gov/cancer/Documents/homemos/Shared10/03/ccsc10-03_att_guideline_cancer_cluster01082010.pdf)

Appendix E: University of Maryland Cancer Epidemiology Alliance Research Clusters



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