



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

July 12, 2013

The Honorable Thomas McLain Middleton
Chairman
Senate Finance Committee
11 Bladen Street, 3 East
Annapolis, MD 21401

The Honorable Peter A. Hammen
Chairman
House Health and Government Operations Committee
6 Bladen Street, Room 241
Annapolis, MD 21401

Dear Chairman Middleton and Chairman Hammen,

I am writing to provide you with an update on the Department's efforts to review the consent form for the use of indoor tanning devices by minors in Maryland.

In this letter I would like provide some background information, review the process used in considering revisions to the consent form, and explain the Department's next steps.

Background

Statute. Chapter 691 (House Bill 1358) of the 2008 session of the Maryland General Assembly states that “[a]n owner employee or operator of a tanning facility may not allow a minor under the age of 18 years to use a tanning device unless the minor’s parent or legal guardian provides written consent on the premises of the tanning facility and in the presence of an owner, employee, or operator of the tanning facility.” Md. Code Ann., Health-Gen. § 20-106(b). The legislation authorizes the Department to adopt regulations to accomplish this goal. *See id.* § 20-106(d).¹

¹ The preamble to House Bill 1358 reflects the concern of the Maryland General Assembly about the use of indoor tanning devices by minors, stating that “It is in the public interest to protect children from the harmful effects of ultraviolet radiation through the use of artificial tanning devices by restricting minors’ access to such devices unless authorized by a physician.”

Regulation. In 2009, after public comment and review by the General Assembly's Joint Committee on Administrative, Executive, and Legislative Review, the Department adopted regulations to implement House Bill 1358.

The regulations mandate that the Department "specify the wording and content of a consent form for the use of tanning devices by minors" and that tanning facilities "shall use the wording and content of the consent form approved by the Department." COMAR 10.52.06.05.

Consent form: In line with the above regulations, facilities have utilized a Department-issued consent form for several years.

The Request to Reconsider the Consent Form

The Department's current review of the consent form for the use of indoor tanning devices by minors has its origins in a written request from the Maryland and DC Society of Clinical Oncology.

In January 2012, on behalf of the Society, Dr. Eric Seifter, Associate Professor of Medicine and Oncology at Johns Hopkins Hospital and the Sidney Kimmel Comprehensive Cancer Center, wrote the Department to request that it review the consent form. (Attachment 1) The Department determined that it would be appropriate to seek public input about potential revisions.

Considering Revisions to the Consent Form

Initial Public Comment Period: On August 14, 2012, the Department requested public comment on the current regulations and the consent form currently in use. Specifically, the Department requested comments on:

- (a) The state of scientific knowledge regarding the health risks associated with tanning devices and their use by minors;
- (b) Information on whether the consent and age verification procedures prescribed by regulation are being carried out, in the experience of consumers and facility operators; and
- (c) Recommendations, with justification, for changes in consent and age verification procedures as prescribed by regulation.

In response to this request, the Department received over 50 comments from a broad range of interest groups, medical professionals, and consumers.

The comments reflected differing viewpoints. On one hand, the medical community generally supported stronger language and photos in the consent form. For example, Dr. Lawrence Green, a practicing dermatologist in Maryland, asked the Department to “add new language that educates the parent as to the serious consequences of indoor tanning,” referencing that the World Health Organization has classified “ultraviolet radiation from tanning beds...as ‘carcinogenic to humans’...in the same category as tobacco and tobacco smoking, mustard gas, and asbestos” and that “a study published in the International Journal of Cancer found...the risk of melanoma [to be] 41% higher for those who had ever used a tanning bed.”

On the other hand, the Maryland Indoor Tanning Association and others disputed evidence of a link to cancer and commented “the current regulations are satisfactory to assure parental consent is obtained.” Similarly, one Maryland mother opposed changing the consent form restrictions since “changing something that is working just fine is pointless.”

Letter to General Assembly. In January 2013, the Department provided an update to Senator Raskin and Del. Reznick on the progress of our effort to review the current consent form. The chairs of the legislative committees, Senator Middleton, and Delegate Hammen, were copied. The letter explained the public comment process underway and noted that the Department was proceeding under existing law and regulation to revise the consent process (Attachment 2).

Children’s Environmental Health and Protection Advisory Council. The Department requested that the Children’s Environmental Health and Protection Advisory Council review the public comments received and provide input. The Council invited stakeholders to present comments and met on February 12, 2013 for discussion.

According to Dr. Clifford Mitchell, Director of the Environmental Health Bureau for the Department and the chair of the Council, the Council did not vote on a specific consent form at the meeting. According to Dr. Mitchell, the Council’s general recommendations were as follows:

- The consent form should use language that is simple, clear, and appropriate for the reading level of those who will be using it. The current language was generally felt to be too complex.
- There should be a clear distinction between the parental signature as a means of providing consent, and the minor’s signature, which should not be viewed as either consent or assent.
- Members of the Council disagreed about the use of pictures in the consent form, although the majority recommended against their use, expressing concern that pictures would be difficult to interpret in the context of the consent process.
- Finally, many Council members (without a vote) expressed considerable concern about the health risks of tanning for minors and strongly urged the Secretary to consider those risks when evaluating the Council’s recommendations.

Proposed Revised Consent Form: Following the Council meeting, the Department proposed a revised consent form for public comment. Along with this revision, the Department released a summary of public comments to date and an explanation of the process. (Attachment 3)

The proposed revision states, in part, “Indoor tanning causes skin cancer. Skin cancer can be fatal. To reduce the risk of skin cancer, the American Academy of Pediatrics recommends that children under age 18 never use indoor tanning devices.”

The revision did not include graphic photos as requested by Med Chi and others in the medical community. It did indicate that consent would be deemed valid for a maximum of six months, consistent with consent forms signed by parents for participation in athletic seasons.

The Department received more than 30 public comments in response to the new proposal. The comments reflect continued disagreement on this topic.

On one hand, the medical community generally argued the proposed approach should be strengthened. The Maryland chapter of the American Academy of Pediatrics, for example, asked that parents be required to sign consent forms for each visit. Dr. Brian Avin, President of Med Chi, wrote that “there is increasing and irrefutable evidence that use of artificial tanning mechanisms creates an elevated risk of skin cancer, particularly among youthful users,” and “urge[d] [the Department] to take all steps within [its] authority to...ensure that they and their parents are fully informed about the risks of these devices.”

On the other hand, the Maryland Indoor Tanning Association, argued that “there is no conclusive scientific proof that tanning causes melanoma.” The American Suntanning Association advised that “there is still no clear direct experimental evidence showing a causative mechanism between UV and melanoma” and that “controlled UV exposures” can help users “gradually develop natural sunscreen...while minimizing the risk of sunburn.” The Maryland Indoor Tanning Association and Sunseekers, submitted a joint petition asserting that “‘indoor tanning causes skin cancer’ is a lie, is false, and purposely misleading.”

In addition, the Maryland Indoor Tanning Association and others contested the Department’s legal authority to revise the existing tanning consent form.

Legal Authority

The Department consulted with the Office of the Attorney General in developing the process of considering revisions to the consent form. After receiving the second round of public comment, which included questions on the Department’s legal authority, I asked the Office of Attorney General to write a letter summarizing its advice on this topic.

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In the letter, Joshua Auerbach, Assistant Attorney General and Principal Counsel for the Department, wrote that “the Department has legal authority to revise the form with the updated and new content under consideration.” (Attachment 4).

Next Steps

Parents deserve the best information when deciding whether to permit their children to use indoor tanning devices. As more scientific evidence becomes available, it is important to consider whether changes to the consent form are appropriate.

While it may not be possible to achieve consensus among all interested parties, the Department will consider all viewpoints before proceeding.

As a next step, the Department intends to take advantage of the extraordinary expertise in Maryland on questions related to children’s health and to cancer.

In September 2013, I anticipate meeting with the Children’s Environmental Health and Protection Advisory Council to provide an update on the public comments received and to receive additional input from members.

Then, at the end of September, the Department will seek the input of the state Council on Cancer Control on key scientific questions at a public meeting.

The Chair of the Council on Cancer Control is Dr. Stanley Watkins, an oncologist at Johns Hopkins. The Council also includes world-renowned experts in cancer, including Dr. William Nelson, Director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins Hospital System, and Dr. Kevin Cullen, the director of the Marlene and Stewart Greenebaum Cancer Center at the University of Maryland. It includes a broad range of clinicians and experts, as well as consumer members. The recently submitted public comments will be provided to the Council members in advance of this meeting.

More details on the plans for the Council on Cancer Control meeting will be available later this summer.

Thank you for your interest in this matter, and please let me know if you have additional questions. I would be happy to meet with you to discuss these issues further.

Sincerely,

A handwritten signature in blue ink, appearing to read "Josh M. Sharfstein".

Joshua M. Sharfstein, M.D.
Secretary