



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

REQUEST FOR PUBLIC COMMENT ON REVISED CONSENT FORM FOR USE OF INDOOR TANNING DEVICE BY A MINOR

The Department of Health and Mental Hygiene plans to revise the consent form that indoor tanning establishments must use to obtain consent from a parent or guardian for the use of a tanning device by a minor. This document summarizes testimony and comments received to date by the Department, as well as recommendations from the Children's Environmental Health and Protection Advisory Council (CEHPAC or "the Council"), and seeks additional public comment on a revised version of the consent form.

Background

In the 2008 legislative session, the General Assembly passed House Bill 1358, under which "[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 on parental informed consent and age verification for minors' use of tanning devices. *See id.* § 20-106(d).

The preamble to House Bill 1358 states that "[m]ore than 2,300,000 teenagers use artificial tanning devices each year" and that the World Health Organization and the American Academy of Pediatrics have taken positions against the use of tanning devices by minors. The preamble also states: "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."

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 the law. Among other things, the regulations mandate that, in obtaining the statutorily-required consent from a parent or guardian for the use of a tanning device by a minor, a tanning facility "shall use the wording and content of the consent form approved by the Department." COMAR 10.52.06.05.

The authority conferred on the Department in § 20-106 of the Health-General Article includes authority to require tanning facilities, in obtaining consent from a parent or guardian, to use a consent form developed by the Department. In adopting COMAR 10.52.06.05, the Department has properly exercised that authority. Neither the Administrative Procedure Act nor the minor tanning statute requires the Department to adopt an additional regulation to specify or revise the precise wording and content of the consent form, particularly where, as here, the form that tanning facilities are required to use is the Department's own form and identified as such.

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On August 14, 2012, the Secretary asked for initial comments on the current regulations and the consent form currently in use. Specifically, the Secretary asked for 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.

Summary of Comments

The state of scientific knowledge regarding the health risks associated with tanning devices and their use by minors.

The Medical and Chirurgical Society submitted an extensive bibliography of recent studies on health risks associated with use of artificial tanning devices, particularly by minors. These included consensus statements from medical associations, reviews and studies all documenting cancer risks associated with exposure to ultraviolet light. Other commenters generally supported and endorsed these findings. The World Health Organization, the American Medical Association, and the American Academy of Dermatology have all supported legislation to ban the use of artificial tanning devices by people younger than 18 years. In addition, a review by the International Agency for Research on Cancer concluded that young adults should be discouraged from using indoor tanning equipment.

Representatives of the Maryland Indoor Tanning Association (MITA) submitted comments contesting the cancer risks identified in these studies, contending that the studies did not adequately take into account natural sunlight exposure. MITA also contended that the World Health Organization report on cancer and artificial tanning has been refuted. However, the Department did not find evidence to support either of these claims. A representative of MITA also reported that the U.S. Food and Drug Administration (FDA), which has authority to implement a ban on artificial tanning for minors, has examined the issue but has not imposed a ban.¹

The American Cancer Society's Cancer Action Network presented testimony about some of the more recent evidence. The testimony discussed data in the American Journal of Public Health (May, 2011) that up to 40% of teenage girls are users of tanning beds.

A pediatric dermatologist and member of the Maryland Chapter of the American Academy of Pediatrics noted that melanomas are increasing 3-7% per year in all age groups, with the biggest rate increase in teenagers. He expressed concern about both indoor and outdoor exposure to ultraviolet light and advocated for a ban on indoor tanning for minors that would be similar to prohibitions on the use of alcohol and tobacco by minors. The physician advocated, alternatively, for a requirement of parental consent at each exposure to artificial tanning.

Finally, some members of MITA urged caution in too tightly regulating commercial tanning devices, because of the possibility that consumers might purchase artificial tanning devices themselves, bypassing all of the regulatory safeguards. There was no information presented on how likely this might be.

¹ These comments were received before May 6, when FDA proposed to add a warning label to tanning beds advising against use by people under 18.

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Whether the consent and age verification procedures prescribed by regulation are being carried out, in the experience of consumers and facility operators

A representative of MITA noted that each year he asks both the Department and the Consumer Protection Division of the Attorney General's office whether there are any complaints related to tanning, and each year there is no evidence of complaints. Tanning salon operators who presented testimony indicated that they closely adhere to the law, asking for signed consent as called for, and often (in the words of some commenters) going beyond the requirements of the law. For instance, all of the tanning operators who presented testimony indicated that they follow all FDA guidelines regarding skin type and tanning, as well as prohibiting tanning at shorter intervals than those recommended by lamp manufacturers.

A number of commenters claimed that tanning salon operators were more likely to adhere to the law than other types of establishments where tanning devices might be found. Although no specific instances were described, concerns were raised that retail establishments and other establishments could be allowing minors to use artificial tanning devices without appropriate consent, age verification, or adherence to FDA rules and guidelines. Neither the Department nor CEHPAC heard any specific details or testimony to support or refute these claims.

Recommendations for changes in consent and age verification procedures

MedChi offered written and oral testimony on changes to improve the regulations, consent form, and age verification procedures. With regard to the consent form and process, MedChi suggested: (1) providing in the form more detailed information about the risk of cancer; (2) utilizing in the form pictorial examples of skin cancer; (3) requiring parental or guardian consent for each encounter, to protect both the parents and the tanning facility; and (4) providing information about the recommended schedule for skin cancer screening. The American Cancer Society's Cancer Action Network also recommended the use of pictures in the consent form, as well as a separate brochure with information about cancer risks. A representative of the Maryland Chapter of the American Academy of Pediatrics advocated for a requirement of parental consent at every visit.

A MITA representative asserted that, as a legal matter, the Department could not alter its current consent form without specifying the new content of its form in a regulation. He also offered several comments on the form itself:

1. The form should be more formal, should have the name and seal of the Department, and look more official.
2. The paragraph describing the expiration should be immediately below where parents indicate their preference for the time period that the student is allowed to use tanning devices.
3. The verification of identity should require a government-issued ID and ID number.

MedChi and MITA representatives, on behalf of their respective organizations, committed at the CEHPAC hearing on tanning to try to develop mutually acceptable language for the consent form. The two organizations did attempt to work out possible language, but this effort was ultimately unsuccessful.

The Children's Environmental Health and Protection Advisory Council evaluated comments from stakeholders and made several recommendations to the Secretary concerning tanning for minors. These recommendations principally concerned the consent form and process, rather than the age verification procedures. They can be summarized as follows:

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1. 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.
2. 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.
3. 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.
4. 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.

The Department's Response

The Department has evaluated all of the comments and information received, and in response is taking the following actions, which are consistent with the recommendations of the Advisory Council. With respect to the consent form, the Department has developed a revised consent form, with the following features:

- The language has been simplified.
- The statement concerning risk and the consensus of the medical community about tanning for minors has been strengthened.
- The parental/guardian consent section has been clearly separated from the section identifying the minor who is the subject of the form.
- The form requires presentation of an official government-issued identification as part of the verification process.
- The form expires after six months.

In addition, the Department recognizes that while many commercial tanning salon operators are operating in conformity with the law, there may be commercial retail facilities subject to the law that are either unaware of the requirements or are not in compliance. Therefore, the Department will seek to identify any such facilities, make them aware of the law, and ask the public to assist it in doing so.

Finally, the Department also proposes that should FDA finalize its proposal for a warning label advising against use by people under 18, the Department would add a summary of FDA's warning to the consent form.

Public Comment

The Department requests public comment on the revised consent form and procedure. The Department will consider all submitted comments before finalizing revisions to the consent form, which is expected in fall 2013. Please submit comments to the Maryland Department of Health and Mental Hygiene, Environmental Health Bureau, Attention Nancy Servatius, 201 West Preston Street, Third Floor, Baltimore, MD 21201. Comments may also be submitted by email to dhmh.envhealth@maryland.gov, or by phone, toll free, at 1-866-703-3266. All comments must be submitted by June 13, 2013.