

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulations  
Department of Health and Mental Hygiene  
(DLS Control No. 14-215)**

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**Overview and Legal and Fiscal Impact**

The proposed regulations govern the licensing and operation of cosmetic surgical facilities that would not otherwise be subject to licensure and regulation as ambulatory surgical facilities.

The proposed regulations present no legal issue of concern.

General fund revenues for the Office of Health Care Quality increase by an estimated \$150,000 from licensure fees paid by cosmetic surgical facilities. General fund revenues may also increase by a minimal amount due to the issuance of administrative penalties for violations. Revenues likely do not accrue until fiscal 2016. In the short term, existing staff is being redirected to conduct licensure and surveying activities, but additional staff may be needed in the out-years.

**Regulations of COMAR Affected**

**Department of Health and Mental Hygiene:**

Adult Health: Cosmetic Surgical Facilities: COMAR 10.12.03.01-.12

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**Legal Analysis**

**Background**

During the week of September 17, 2012, the Department of Health and Mental Hygiene began investigating a cluster of three severe invasive Group A *Streptococcus* infections in individuals who recently had liposuction at a cosmetic surgery facility in Timonium. All three patients were hospitalized; one subsequently died. An investigation revealed that the facility lacked effective infection control procedures and, as a result, the department and Baltimore County ordered the facility closed on September 18, 2012. The outbreak raised questions about the adequacy of oversight of cosmetic surgery procedures. In response to this incident, Chapter 398 of 2013 was enacted. The law became effective October 1, 2013, and authorizes the Secretary of Health and Mental Hygiene to adopt regulations to regulate cosmetic surgical facilities.

**Summary of Regulations**

The Department of Health and Mental Hygiene is adding COMAR 10.12.03 to regulate cosmetic surgical facilities.

Regulation .01 contains definitions for the chapter and includes terms such as “cosmetic surgical facility” and “cosmetic surgical procedure.”

Regulation .02 prohibits a person from establishing or operating a cosmetic facility without obtaining a license from the Secretary. A license is valid for three years from the date of issuance, unless it is suspended or revoked by the Secretary. An applicant is required to submit a nonrefundable fee of \$3,000 with an application for initial or renewal licensure. A license is not transferrable.

Regulation .03 specifies the licensing procedures. A person who wants to operate a cosmetic surgical facility must either (1) be in compliance with all federal, State, and local laws and be accredited by the American Association for Accreditation of Ambulatory Surgical Facilities, the Accreditation Association for Ambulatory Health Care, the Joint Commission, or an accreditation organization approved by the Secretary; or (2) be certified to participate in the Medicare program. Additionally, the person must file an application, pay the licensure fee, and submit to an initial survey on request by the department. The regulation also specifies who is required to apply for a license on behalf of certain entities. Based on information provided by the applicant and the department's own investigation, the Secretary is required to (1) approve the application unconditionally if all requirements are met; (2) approve the application conditionally; or (3) deny the application if the applicant has been convicted of certain crimes or does not comply with the requirements for licensure. The Secretary is authorized to deny a license under certain circumstances, including if an individual applicant engaged in conduct that caused the revocation of a prior license or an individual applicant held a position as an owner, director, or officer in a corporate entity that had its license revoked. The Secretary must consider the factors identified in Regulation .10C when determining whether to deny a license. A person aggrieved by a decision of the Secretary under the regulation can appeal the action by filing a request for a hearing in accordance with Regulation .12. A license may be renewed for an additional three-year period. Additionally, the Secretary may, under certain circumstances, issue a temporary license for a period not exceeding one year, unless the period is extended for good cause. Finally, the regulation specifies that the transfer or assignment of a license is prohibited and the circumstances under which a license must be returned to the Secretary.

Regulation .04 specifies that the licensee is responsible for compliance with all laws and regulations applicable to the operation of a cosmetic surgical facility, including a physician's compliance with § 14-404(a)(41) of the Health Occupations Article. Section 14-404(a)(41) provides that the Board of Physicians can discipline a physician who performs a cosmetic surgical procedure in an office or a facility that is not accredited by certain organizations or certified to participate in the Medicare program. The licensee is required to meet the standards for operation that are issued by the licensee's accreditation organization. If the licensee loses its accreditation, the licensee must immediately cease operations, notify the department, and return the license certificate to the department.

Under Regulation .05, the Secretary can investigate complaints concerning the conformance of a facility to the requirements of the regulations and for compliance with the standards for the operation of a cosmetic surgical center issued by its accreditation organization. A facility must be open during normal business hours, and any other times that the facility is serving patients, for inspection by the department and any other agency designated by the Secretary to investigate complaints. Complaints concerning a health care practitioner's performance or conformance to medical practice standards must be referred to the appropriate health occupations board. If the Secretary determines that a licensee fails to meet the requirements of the regulations or fails to comply with the operating standards issued by its accreditation organization, the Secretary must advise the licensee of the exact nature of the violation, require the facility to specify

the corrective action it is taking and monitor, and monitor the facility to ensure that it takes corrective action. The Secretary, however, cannot specify that a licensee correct a violation of a standard that is a higher standard than that required of an ambulatory surgical facility. The facility is required to make its records and reports available to the department or its designee for inspection during an investigation and must immediately provide photocopies or electronic images of records and reports on request.

Regulation .06 requires a facility to maintain a complete, comprehensive, and accurate medical record for a patient. The regulation also specifies what information must be included, at a minimum, in the record. A facility is required to (1) send a copy of the record with the patient on referral to another health care provider or on transfer to a hospital; (2) use the medical record, if appropriate, in instructing the patient and the family; and (3) comply with all disclosure requirements in Title 4, Subtitle 3 of the Health – General Article.

Regulation .07 governs patient's rights. The administrator of the facility is required to ensure that the facility develops and implements written policies and procedures concerning patients' rights and responsibilities. The facility must make the policies and procedures available to patients, guardians, and other health care decision makers, as well as the public. The policies and procedures must ensure that (1) the facility informs patients of services that are available and the charges for services not covered by third-party payors; (2) a qualified health care practitioner informs patients of their medical conditions unless medically contraindicated as documented in their medical records; (3) all patients are afforded an opportunity to participate in planning their medical treatments and to refuse to participate in experimental research; and (4) all patients are ensured confidential treatment of their medical records and may approve or refuse release of records to any individual outside the facility, except as provided by law.

Regulation .08 requires a facility to meet all federal, State, and local laws for construction of the facility's physical environment. The facility must also meet all safety requirements of the National Fire Protection Association NFPA 101 "Life Safety Code." Finally the regulation requires the facility to meet the requirements for the handling, treatment, and disposal of special medical wastes as provided in COMAR 10.06.06.

Under Regulation .09, the Secretary may immediately suspend a license on a finding that the public health, safety, or welfare requires emergency action. The department must deliver a written notice to the licensee that (1) informs the licensee of the emergency suspension; (2) gives the reasons for the action and the regulation or regulations with which the licensee has failed to comply that form the basis for the emergency suspension; and (3) notifies the licensee of the right to request a hearing and be represented by counsel. The filing of a hearing request does not stay the suspension. When a licensee is immediately suspended, the licensee must immediately return the license certificate to the department and stop providing services immediately. If a request for a hearing is filed, the Office of Administrative Hearings must conduct a hearing in accordance with Regulation .12 and issue a proposed decision within ten business days of the close of the hearing record. Exceptions may be filed by an aggrieved person pursuant to COMAR 10.01.03. The Secretary, however, must make a final decision pursuant to COMAR 10.01.03. If the Secretary's final decision does not uphold the emergency suspension, the licensee may resume operation.

Regulation .10 requires the Secretary, for good cause shown, to notify a licensee of the decision to revoke the facility's license. The revocation is stayed if a hearing is requested. The Secretary can revoke a license if the licensee (1) has been convicted of a felony that relates to

Medicaid or Medicare or a crime involving moral turpitude; (2) does not comply with the requirements of the chapter; (3) fails to comply with the standards for the operation of a cosmetic surgery facility issued by its accreditation organization; or (4) engages in conduct that requires revocation to protect the public health, safety, or welfare. When considering whether to revoke a license, the Secretary must consider certain factors, including (1) the number, nature, and seriousness of the violations; (2) the extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months; and (3) the degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility. The Secretary must notify the facility in writing of the revocation and the notice must contain certain information, including the effective date of the revocation, the reason for the revocation, and the regulations with which the licensee has failed to comply that form the basis for the revocation. A party aggrieved by the action of the Secretary under the regulation can appeal the action by filing a request for a hearing.

Regulation .11 authorizes the Secretary to impose an administrative penalty of up to \$1,000 for a violation of any provision of the regulations. When considering whether to impose the penalty and the amount of the penalty, the Secretary is required to consider factors very similar to the factors required to be considered when deciding whether to revoke a license. A person aggrieved by the action of the Secretary under the regulation may appeal the action by filing a request for a hearing.

Regulation .12 governs hearings. A request for a hearing must be filed with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality, not later than 30 days after receipt of notice of the Secretary's action. The request must include a copy of the Secretary's action. The hearing must be conducted in accordance with the Administrative Procedure Act, COMAR 28.02.01, and COMAR 10.01.03. The burden of proof is as set forth in COMAR 10.01.03.28. The burden of proof under that provision depends on what action is being appealed. Unless otherwise stated in the chapter, the Office of Administrative Hearings is required to issue a proposed decision within the time frames set forth in COMAR 28.02.01. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35 and the Secretary is required to issue a final decision in accordance with COMAR 10.01.03.35.

## **Statutory Authority and Legislative Intent**

The department cites Title 19, Subtitle 3C of the Health – General Article as legal authority for the regulations. More specifically, § 19-3C-01 contains definitions used in the subtitle. Section 19-3C-02 authorizes the Secretary to adopt regulations for cosmetic surgical facilities in the State. Regulations adopted by the Secretary must include deeming a facility to meet specified requirements if the facility is accredited by (1) the American Association for Accreditation of Ambulatory Surgical Facilities; (2) the Accreditation Association for Ambulatory Health Care; (3) the Joint Commission; or (4) any other accreditation organization as determined by the Secretary. The section also states that the regulations cannot require higher standards for cosmetic surgical facilities than the standards required for ambulatory surgical facilities under Title 19, Subtitle 3B of the Health – General Article. The section also authorizes the Secretary to adopt regulations that establish circumstances under which a procedure that would otherwise not meet the definition of “cosmetic surgical procedure” would be included. Finally, § 19-3C-03 authorizes the Secretary to investigate complaints concerning the conformance of a cosmetic surgical facility to the requirements of the regulations adopted under § 19-3C-02. The section also requires that a complaint be referred to the appropriate health occupations board if the complaint concerns health care practitioner performance or standards of medical practice.

## **Technical Corrections and Special Notes**

The department was contacted regarding several issues with the regulations and will make several changes to them before they are published in the *Maryland Register*. Two changes were substantive in nature. First, a definition of “person” will be added for clarity. Second, Regulation .04 will be amended to clarify that the licensee is responsible for physician compliance with § 14-404(a)(41) of the Health Occupations Article. The original language indicated that the provision of the Health Occupations Article was a requirement with which cosmetic surgical facilities had to comply. Other changes clarify language. For example, Regulation .05D(3) will be changed to read “[t]he Secretary may not require that a licensee correct a violation...” rather than “[t]he Secretary may not specify that a licensee correct a violation...” Additionally, corrections to grammatical errors and cross-reference errors will be made. The changes also are reflected in the description of the regulations above.

## **Fiscal Analysis**

General fund revenues for the Office of Health Care Quality increase by an estimated \$150,000 from licensure fees paid by cosmetic surgical facilities. General fund revenues may also increase by a minimal amount due to the issuance of administrative penalties for violations. Revenues likely do not accrue until fiscal 2016. In the short term, existing staff is being redirected to conduct licensure and surveying activities, but additional staff may be needed in the out-years.

## **Agency Estimate of Projected Fiscal Impact**

The regulations implement Chapter 398 of 2013 (HB 1009 of 2013), which authorizes the Secretary of Health and Mental Hygiene to adopt regulations to regulate cosmetic surgical facilities. The department advises that general fund revenues increase by \$150,000 based on an estimated 50 cosmetic surgical facilities seeking licensure at a fee of \$3,000 for a three-year period. The department estimates that license applications and the associated revenues will not be submitted until early fiscal 2016. The Department of Legislative Services concurs.

As noted in the fiscal and policy note for HB 1009 of 2013, general fund expenditures for the office likely increase. The department advises that an estimated 2.5 to 3.0 surveyors are needed to conduct licensure and surveying activities for cosmetic surgical centers; however, the department specifies that existing staff and budgeted general funds are being redirected to this purpose.

## **Impact on Budget**

Although general fund revenues increase, likely beginning in fiscal 2016 and every three years thereafter, the budget for the Office of Health Care Quality is not likely affected in the short term, particularly since the department advises that existing staff is being redirected to conduct licensure and surveying activities. To the extent additional staff is needed, however, general fund expenditures increase in the out-years – by as much as \$200,000.

## **Agency Estimate of Projected Small Business Impact**

The department advises that the regulations have a meaningful economic impact on small businesses in the State. The Department of Legislative Services concurs. In addition to the \$3,000 State licensure fee, the regulations require cosmetic surgical facilities to be accredited by an approved organization. Accreditation through the Joint Commission (one of several such organizations) costs \$9,430 for a three-year cycle of accreditation. Thus, in total, a cosmetic surgical facility incurs costs of up to \$12,430 for a three-year licensure and accreditation cycle. Cosmetic surgery facilities that already have accreditation incur lesser expenses.

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