

4501-45-02

Certification requirements for immobilizing or disabling devices other than ignition interlock devices.

- (A) A manufacturer of an immobilizing or disabling device, other than an ignition interlock device, shall obtain certification from the director for each device model or type that differ in any aspect, prior to leasing, selling, or otherwise using its device(s) in this state.
- (B) A manufacturer of an immobilizing or disabling device, other than an ignition interlock device, may not be eligible for certification of its device(s) if the manufacturer, including, but not limited to the owner(s), officers, partners, members, agents, employees, contractors, or installers:
- (1) Is an employee, or immediate family member of an employee, of the department or the department of health;
 - (2) Has a felony conviction, an operating a vehicle while intoxicated conviction, or a conviction for any crime involving dishonesty, deceit, or fraud.
- (C) A manufacturer of an immobilizing or disabling device, other than an ignition interlock device, shall request, in writing, an application for certification from the department. The application for certification shall be on a format prescribed by the director as listed in paragraph (D) of rule 4501-45-11.
- (1) A manufacturer shall file with the director a separate and complete application for certification for each device model or type that differ in any aspect, together with all documents required by the application, paragraphs (D) and (E) of this rule, and the rules of this chapter.
 - (2) At the time a manufacturer of an immobilizing or disabling device, other than an ignition interlock device, files its application for certification with the director, together with all documents required by the application and the rules of this chapter, the manufacturer shall pay a certification fee of one hundred dollars, in the form of a check or money order, payable to the treasurer of the state of Ohio. The certification fee is non-refundable.
 - (3) The director shall have the authority to request a computerized criminal history for any person identified in a manufacturer's application for certification or any person identified in any document filed with the application. The manufacturer shall pay all costs for the computerized criminal history.
- (D) In addition to the completed application, and all required documents, a manufacturer of an immobilizing or disabling device, other than an ignition interlock device,

shall file with the director:

- (1) A complete copy of the testing protocol for the specific device model or type that is the subject of the manufacturer's application for certification, and the results thereof, conducted by an independent testing laboratory. The testing protocol, and the results, shall be reviewed and approved by the director of health;
 - (2) A copy of the manufacturer's certificate of product liability insurance for the specific device model or type, that is the subject of the manufacturer's application for certification, which shall:
 - (a) Identify the manufacturer;
 - (b) Identify the department as an additional insured and certificate holder;
 - (c) Identify the policy number;
 - (d) State a policy limit of at least one million dollars per occurrence;
 - (e) State the effective date and the expiration date of the policy;
 - (f) State that should the policy be cancelled before the expiration date, the issuing insurer will provide written notice to the department at least thirty days before cancellation of the policy.
- (E) The director shall notify a manufacturer, in writing, by certified mail, return receipt, whether certification of the immobilizing or disabling device, other than an ignition interlock device, which is the subject of the manufacturer's application is granted or denied.
- (1) If certification is granted, a manufacturer shall receive a certificate from the director. The certificate shall be on a format prescribed by the director. Certification of the specific immobilizing or disabling device, other than an ignition interlock device, shall remain in effect unless the director suspends or revokes the certification pursuant to rule 4501-45-05 of the Administrative Code.

When the director issues a certificate to a manufacturer of an immobilizing or disabling device, other than an ignition interlock device, the department shall add the certified device model or type, together with the manufacturer's name, business address, and contact information, to the department's list of licensed

manufacturers of ignition interlock devices and certified devices published on the department's website.

If a manufacturer of a certified immobilizing or disabling device, other than an ignition interlock device, changes any of the information published on the department's website, the manufacturer shall immediately notify the department, in writing, and the department will update its website.

- (2) The director shall deny certification of an immobilizing or disabling device, other than an ignition interlock device, for any reason(s) set forth in rule 4501-45-05 of the Administrative Code. If certification is denied, a manufacturer shall receive a written notice, by certified mail, return receipt, from the director stating the reason(s) certification was denied.

- (F) If a manufacturer of an immobilizing or disabling device, other than an ignition interlock device, makes any modification(s) to a certified device model or type, the manufacturer shall immediately notify the director, in writing by certified mail, return receipt, of each modification and the reason(s) for the modification(s).

In addition to the notice, the manufacturer shall provide the director with a complete copy of the testing protocol for the modified device, and the results thereof, conducted by an independent testing laboratory. The testing protocol, and results, shall be reviewed and approved by the director of health.

The director shall determine whether the certification in effect at the time of the notice of modification(s) applies to the modified immobilizing or disabling device, other than an ignition interlock device, or the manufacturer must apply for a separate certification of the modified device. The director shall notify the manufacturer of the decision by certified mail, return receipt.

- (G) A manufacturer of an immobilizing or disabling device, other than an ignition interlock device, shall obtain product liability insurance coverage for each device model or type that differ in any aspect prior to filing its application for certification with the director. The manufacturer's product liability insurance coverage shall meet the requirements set forth in paragraph (D)(2) of this rule.

- (H) If a manufacturer's product liability insurance for a certified immobilizing or disabling device, other than an ignition interlock device, is modified prior to the expiration date stated on the certificate of liability insurance previously provided to the director, the manufacturer shall provide the director with a copy of the manufacturer's modified certificate of liability insurance coverage which complies with all requirements set forth in paragraph (D)(2) of this rule by certified mail, return receipt, postmarked no later than three days after the date the modified product liability insurance becomes effective.

- (I) If a manufacturer's product liability insurance coverage for a certified immobilizing or disabling device, other than an ignition interlock device, is cancelled by its insurer, or terminated by the manufacturer prior to the expiration date stated on the certificate of liability insurance previously provided to the director, the manufacturer shall provide the director with a copy of the manufacturer's new certificate of product liability insurance which complies with all requirements set forth in paragraph (D)(2) of this rule, by certified mail, return receipt, postmarked no later than three days after the manufacturer received the notice of cancellation or termination.

- (J) If a manufacturer of a certified immobilizing or disabling device, other than an ignition interlock device, allows any time lapse in its product liability insurance coverage, or fails to provide all documents required by paragraph (D)(2) and paragraphs (G) to (I) of this rule, the director shall suspend or revoke the manufacturer's certification(s) pursuant to rule 4501-45-05 of the Administrative Code. The director shall notify the manufacturer of the certification suspension(s) or revocation(s) by certified mail, return receipt.

- (K) If a manufacturer's certification(s) of its immobilizing or disabling device(s), other than an ignition interlock device, is suspended or revoked pursuant to rule 4501-45-05 of the Administrative Code, the director shall remove the manufacturer's name, business address, contact information, and certified device(s) from the department's list of licensed manufacturers of ignition interlock devices and certified devices published on the department's website.

Effective: 04/01/2016

Five Year Review (FYR) Dates: 01/15/2016 and 03/21/2021

CERTIFIED ELECTRONICALLY

Certification

03/21/2016

Date

Promulgated Under: 119.03
Statutory Authority: 4510.43
Rule Amplifies: 4510.43
Prior Effective Dates: 12/31/2010