

4501-45-04

Certification requirements for ignition interlock devices.

- (A) Upon obtaining a license from the department pursuant to rule 4501-45-03 of the Administrative Code, a manufacturer of an ignition interlock device is immediately eligible to apply for certification from the director for each ignition interlock device model or type that differ in any aspect intended for lease, sale, or other use in this state.
- (B) A manufacturer of an ignition interlock device may not be eligible for certification of its device(s) if any of the manufacturer's owner(s), officers, partners, 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 been convicted of, pled guilty to, had a judicial finding of guilt for, or had a judicial finding of eligibility for treatment in lieu of conviction for, any of the following:
 - (a) Any felony within ten years of the date of application;
 - (b) A misdemeanor, other than a minor misdemeanor, within five years of the date of application that is reasonably related to a person's ability to serve safely and honestly in connection with ignition interlock devices;
 - (c) A violation of any federal, state, county, or municipal ~~narcotics~~drug law;
 - (d) Any act committed in another state or jurisdiction that, if committed in Ohio would constitute a violation set forth in this paragraph.
- (C) A manufacturer of an ignition interlock device shall request, in writing, an original or renewal application for certification from the department. The original and renewal applications for certification of an ignition interlock device shall be on a format prescribed by the director as listed in paragraph (D) of rule 4501-45-11 of the Administrative Code. Renewal application shall be submitted to the department thirty days prior to certification expiration.
- (1) A manufacturer of an ignition interlock device shall file with the director a separate and complete, original or renewal application for certification, for each ignition interlock device model or type that differ in any aspect, intended for lease, sale or other use in this state.
 - (2) At the time a manufacturer of an ignition interlock device files its original or renewal application for certification with the director, together with all required documents, the manufacturer shall pay a certification fee of one hundred dollars, in the form of a check or money order, made payable to the treasurer

of the state of Ohio. A manufacturer shall pay a separate certification fee with each application for certification filed with the director. The certification fee is non-refundable.

- (3) ~~The director shall have the authority to request a computerized criminal history for any person identified in the manufacturer's application for certification or any person identified in any documents filed with the application. The manufacturer shall pay all costs for the computerized criminal history.~~ The manufacturer is responsible for obtaining a criminal background check for any person identified in the manufacturer's application for certification, any person identified in any documents filed with the manufacturer's application, and any person who installs, services, monitors, or removes the manufacturer's ignition interlock devices. The criminal background check shall be obtained within two weeks of beginning to provide the specified services and at least every three years thereafter.
- (4) Upon request of the department, the criminal background check of any person referenced in paragraph (C)(3) shall include a request to the bureau of criminal identification and investigation to conduct a criminal records check that includes information from the federal bureau of investigation. The manufacturer shall pay all costs for the criminal background check. The criminal background check shall be submitted to the department and not be dated more than forty-five days from the request.
- (D) In addition to the completed original or renewal application, and all required documents, a manufacturer of an ignition interlock device shall file with the director:
- (1) A certificate from an independent testing laboratory indicating that the ignition interlock device that is the subject of the manufacturer's application meets or exceeds the standards of the "National Highway Traffic Safety Administration (NHTSA), Department of Transportation, as published in Volume 78 No. 89 of the Federal Register on May 8, 2013 (78 F.R. 26849, 2013)" attached as an appendix to this rule, and incorporated as if fully rewritten herein, or any modifications thereto, in effect at the time of the director's decision regarding certification of the device;
- (a) Require the operator of the vehicle to submit to a random retest within ten minutes of starting the vehicle. A random retest must continue at intervals not to exceed fifteen minutes after the previous retest for the duration of the travel. An operator shall have six minutes to perform the retest and accept unlimited samples within the time frame;

- (b) Allow a minimum of 1.5 L of breath for an acceptable breath sample and permit 1.2 L upon medical recommendation;
 - (c) The device shall be calibrated to a set-point of twenty-five thousandths per cent breath alcohol concentration, with consideration to drivers under twenty-one years of age;
 - (d) The device may contain a digital image identification device and/or GPS provided these features will not distract or impede the driver in any manner from safe and legal operation.
 - (e) Maintain minimum calibration stability period of thirty-seven days (thirty days plus seven-day lockout countdown) and not to exceed sixty-seven days (sixty days plus seven-day lockout countdown).
 - ~~(f) All certified ignition interlock devices for lease, sale, or other use in the state of Ohio, must be compliant with this paragraph on or before April 1, 2017.~~
- (2) A complete quality assurance plan in accordance with appendix A of the NHTSA standards referenced in paragraph (D)(1) of this rule.
- (3) A complete copy of the testing protocol, and the results thereof, conducted by an independent testing laboratory, for the ignition interlock device which is the subject of the manufacturer's original application for certification. The testing protocol, and results, shall be reviewed and approved by the director of health;
- (4) A copy of the manufacturer's certificate of product liability insurance for the ignition interlock device model or type which 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 if the policy is ~~cancelled~~canceled before its expiration date, the issuing insurer will provide written notice to the department at least thirty days before cancellation of the policy.

(E) In addition to the completed application, and required documents, a manufacturer shall certify by affidavit to the director that the specific ignition interlock device which is the subject of the application for certification complies with each of the following:

- (1) It contains a minimum and maximum calibration range, in accordance with the NHTSA standards referenced in paragraph (D)(1) of this rule;
- (2) It does not impede the safe operation of the vehicle;
- (3) It has features that are operating and functioning, and that make circumvention difficult, and that do not interfere with the normal use of the vehicle;
- (4) It correlates well with established measures of alcohol impairment;
- (5) It works accurately and reliably in an unsupervised environment;
- (6) It is resistant to tampering and shows evidence of tampering if tampering is attempted;
- (7) It is difficult to circumvent and requires premeditation to do so;
- (8) It minimizes inconvenience to a sober user;
- (9) It requires a proper, deep-lung breath sample or other accurate measure of the concentration by weight of alcohol in the breath;
- (10) It operates reliably over the range of automobile environments;
- (11) It is made by a manufacturer who is covered by product liability insurance.

(F) The director shall notify a manufacturer, in writing, by certified mail, return receipt, whether certification of the ignition interlock device model or type, that 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 ignition interlock device shall expire one year from the date of issuance stated on the certificate, unless certification is suspended or revoked pursuant to rule 4501-45-05 of the Administrative Code prior to the expiration date stated on the certificate.

When the director issues a certificate to a manufacturer of 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 as listed in paragraph (F) of rule 4501-45-11 of the Administrative Code.

If a manufacturer of a certified 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 ignition interlock device for any reason(s) set forth in rule 4501-45-05 of the Administrative Code or the rules of this chapter. If certification is denied, a manufacturer shall receive written notice, by certified mail, return receipt, from the director stating the reason(s) certification was denied.

- (G) If a manufacturer of 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 may be required to 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 the 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 certified ignition interlock device or if 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.

- (H) If a manufacturer's product liability insurance coverage for any certified ignition interlock device is modified by its insurer, or the manufacturer, prior to the expiration date as stated on the certificate of product liability insurance provided to the director pursuant to paragraph (D)(3) of this rule, the manufacturer shall provide the director with the following, by certified mail, return receipt, within five days of receiving its notice of modification:

- (1) A written statement from the manufacturer detailing the circumstances and reason(s) for the modification of its product liability insurance;
- (2) A copy of the manufacturer's modified certificate of product liability insurance which complies with all requirements set forth in paragraph (D)(3) of this rule.

- (I) If a manufacturer's product liability insurance coverage for a certified ignition interlock device is ~~cancelled~~canceled by its insurer, or terminated by the manufacturer, prior to the expiration date stated on the certificate of product liability insurance previously provided to the director, the manufacturer shall provide the director with the following, by certified mail, return receipt, within five days of receiving its notice of cancellation or termination:
- (1) A written statement from the manufacturer detailing the circumstances and reason(s) for cancellation, or termination, of its product liability insurance coverage;
 - (2) A copy of the manufacturer's new certificate of liability insurance which complies with all requirements set forth in paragraph (D)(3) of this rule.
- (J) If a manufacturer of an ignition interlock device allows any time lapse in its product liability insurance coverage, or fails to provide all documents required by paragraphs (D)(3), (H), and (I) of this rule, the director shall suspend or revoke the manufacturer's license and certification(s). The director shall notify the manufacturer of the suspension(s) or revocation(s) by certified mail, return receipt.
- (K) ~~If a manufacturer's certification(s) of its ignition interlock device(s) is suspended or revoked, 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.~~ The manufacturer is responsible for ensuring that each installer of the manufacturer's ignition interlock device is adequately trained and qualified to install, calibrate, and perform monitoring checks of each ignition interlock device.
- (L) No manufacturer or installer shall engage in any conduct involving dishonesty, fraud, deceit, misrepresentation, incompetence or other conduct that may reasonably be interpreted as unethical.
- (M) The manufacturer shall maintain a list of all persons who install, service, monitor, or remove ignition interlock devices.
- (N) Manufacturers shall review each installation site at least annually to ensure that installers are following all applicable laws and rules, and that the installer's operations are consistent with the manufacturer's specifications.
- (O) Each installation site shall maintain a professional, cleanly appearance.
- (P) Under no circumstances will the offender be allowed to watch the installation of the ignition interlock device. Adequate security measures shall be taken to ensure that

areas where installations of ignition interlock devices occur shall not be visible to the offender.

(Q) The installer shall train the offender on the operation of the device at the time of initial installation.

(R) Unless otherwise specified by the court supervising the offender, the manufacturer or installer shall inspect and monitor each ignition interlock device every thirty days. The offender will be given a seven day grace period to have the device inspected.

(S) Manufacturers and installers shall ensure that ignition interlock events are reported to the court within two business days of detection, and provide testimony before the court as needed regarding any ignition interlock events. Ignition interlock events include the following:

(1) A breath sample indicating the presence of alcohol in the offender's breath in a concentration sufficient to prevent the ignition interlock device from allowing the motor vehicle to be started;

(2) A breath sample during a rolling retest indicating the presence of alcohol in the offender's breath in a concentration that would have been sufficient to prevent the ignition interlock device from allowing the motor vehicle to be started;

(3) The offender's failure to appear for a monitoring check within the timelines specified in paragraph (R);

(4) The offender's failure to submit to a rolling retest;

(5) The device was tampered with or circumvented.

(T) Manufacturers and installers shall respond to offender requests for technical assistance with the device as soon as practicable.

(U) Manufacturers shall comply with all terms and conditions set forth in department orders or consent agreements.

(V) Any failure to comply with any law or rule involving the licensing and certification of ignition interlock devices or other immobilizing or disabling device that is committed by an installer shall be attributable to the manufacturer.

Effective: 1/1/2018

Five Year Review (FYR) Dates: 3/21/2021

CERTIFIED ELECTRONICALLY

Certification

12/22/2017

Date

Promulgated Under: 119.03

Statutory Authority: 4510.45

Rule Amplifies: 4510.43

Prior Effective Dates: 09/06/1988 (Emer.), 07/22/1990, 08/24/2003,
12/31/2010, 04/01/2016