

4501-45-01

Definitions.

- (A) "Days" means business days and excludes weekends and [government](#) holidays.
- (B) "Department" means the department of public safety.
- (C) "Director" means the director of the department of public safety or a designee.
- (D) "Director of Health" means the director of the department of health or a designee.
- (E) "Ignition interlock device" means a device ~~certified by the director~~ that connects a breath analyzer to a motor vehicle's ignition system, that is constantly available to monitor the concentration by weight of alcohol in the breath of any person attempting to start the motor vehicle by using its ignition system, and that deters starting the motor vehicle by use of its ignition system unless the person attempting to start the vehicle provides an appropriate breath sample for the device and the device determines that the concentration by weight of alcohol in the person's breath is below a preset level.
- (F) "Immobilizing or disabling device" means a device ~~certified by the director~~ that a person may be court ordered to use as a condition of exercising limited driving privileges. "Immobilizing or disabling device" includes, but is not limited to an ignition interlock device, an ignition blocking device initiated by time or magnetic or electronic encoding, an activity monitor, a prototype device that is used according to protocols designed to ensure efficient and effective monitoring of court ordered limited driving privileges granted to a person and any other device that reasonably assures compliance with a court order granting limited driving privileges.
- (G) "Independent testing laboratory" means a testing laboratory or analytical chemist not affiliated with a manufacturer of immobilizing or disabling devices including, but not limited to ignition interlock devices, that is qualified to test such devices or reference samples, and is ~~approved by the department~~ [accredited to the ISO 17025 laboratory management standard listed in paragraph \(A\) of rule 4501-45-11.](#)
- (H) "Manufacturer" means any natural person, firm, partnership, association, corporation, or other business entity, engaged in the manufacturing or assembling of an immobilizing or disabling device, including an ignition interlock device.
- (I) "Prototype device" means an alcohol testing device, not certified by the director, that a court uses in a pilot program to monitor limited driving privileges granted to a person.

- (J) "Purchaser" includes, but is not limited to a natural person, a corporation, a partnership, a limited liability company, an association, or any other entity comprised of two or more persons having a joint or common interest, that leases, buys, or otherwise uses a licensed manufacturer's ignition interlock device(s) in this state.

- (K) "Sales" means all monetary profit a licensed manufacturer of an ignition interlock device earned from, or which is attributed to, the lease, sale, or ~~other~~ use of each of its certified device(s) to purchasers in this state during the twelve month period the manufacturer's license was in effect.

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.

4501-45-03

Licensing requirements for manufacturers of ignition interlock devices.

- (A) A manufacturer of an ignition interlock device that intends to lease, sell, or otherwise use its ignition interlock device(s) in this state shall annually obtain first a license from the department, and then certification from the director for each ignition interlock device model or type that differ in any aspect.
- (B) A manufacturer of an ignition interlock device may not be eligible for a license 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 a felony conviction, an operating a vehicle while intoxicated conviction or a drug-related conviction, regardless of when or where the conviction occurred, a parole/probation violation, or a conviction for any crime involving dishonesty, deceit or fraud.~~ 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 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 licensing from the department. The original and renewal applications for licensing shall be on a format prescribed by the director as listed in paragraph (C) of rule 4501-45-11.
- (1) A manufacturer of an ignition interlock device shall file with the department a complete, original or renewal application for licensing, together with all documents required by the application, and the rules of this chapter.
 - (2) At the time a manufacturer of an ignition interlock device files its original or renewal application for licensing with the department, and all required documents, the manufacturer shall pay a licensing fee of one hundred dollars,

in the form of a check or money order, payable to the treasurer of the state of Ohio. The licensing fee is non-refundable.

- (3) The department shall have the authority to request a computerized criminal history for any person identified in the manufacturer's application for licensing or any person identified in any documents filed with the application. The manufacturer shall pay all costs for the computerized criminal history.
- (D) The department shall notify a manufacturer of an ignition interlock device, in writing, by certified mail, return receipt, whether a license is granted or denied.
- (1) If a license is granted, a manufacturer of an ignition interlock device will receive a license from the department on a format prescribed by the director. The license shall expire one year from the date of issuance stated on the license, unless the license is suspended or revoked pursuant to rule 4501-45-05 of the Administrative Code prior to the expiration date stated on the license.
 - (2) A licensed manufacturer is immediately eligible to apply for certification, pursuant to rule 4501-45-04 of the Administrative Code, for each ignition interlock device model or type that differ in any aspect, and which is intended for lease, sale, or any other use in this state.
 - (3) When the department issues a license to a manufacturer of an ignition interlock device, the department shall add 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 licensed manufacturer of 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.
- (E) The department shall deny a license to a manufacturer 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 a license is denied, a manufacturer shall receive a written notice, by certified mail, return receipt, from the department stating the reason(s) the license was denied.

A manufacturer whose license application is denied by the department may appeal the department's denial of a license pursuant to ~~paragraph (A) of~~ rule 4501-45-06 of

the Administrative Code.

(F) A manufacturer of an ignition interlock device that is issued a license by the department shall file an annual report with the department, on a format prescribed by the director, and pay an annual report fee, not later than thirty days after the date the manufacturer's license expires.

(1) The annual report shall state the amount of net profit a licensed manufacturer earned for each certified ignition interlock device model or type from the sales of its certified devices to purchasers in this state during the one year period its license was in effect. A licensed manufacturer shall pay to the department an annual report fee equal to five per cent of the net profit stated in its annual report. The fee shall be in the form of a check or money order and made payable to the treasurer of the state of Ohio.

(2) A licensed manufacturer shall file its annual report with the department not later than thirty days after the date the manufacturer's license expires. A manufacturer may file its annual report with the department by electronic mail, by facsimile, or by certified mail, return receipt, postmarked not later than thirty days after the date the manufacturer's license expires.

(3) If a licensed manufacturer of an ignition interlock device fails to timely file its annual report with the department, timely pay the total annual report fee due to the department, and/or files with the department an annual report containing incorrect or erroneous information, the director shall immediately remove the manufacturer's name, business address, contact information, and certified ignition interlock device(s) from 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](#).

A manufacturer of an ignition interlock device shall be ineligible for a renewal application for licensing until the manufacturer fully complies with all requirements set forth in this rule.

(G) A manufacturer shall notify the department in writing if a device certified for use in Ohio is or has been suspended, revoked, or denied in another state, whether such action occurred before or after approval in Ohio or if and when an appeal to the action(s) was made and the outcome of the appeal. This notification shall be made in a timely manner not to exceed 30 days after the manufacturer has received notice of suspension, revocation, or denial of certification of the device, whether or not the action is or has been appealed. Failure to notify the department may result in suspension, revocation, or denial of certification of the device in Ohio.

(H) Should a manufacturer change its legal business name, be acquired by another manufacturer, or merge with another manufacturer, the manufacturer shall reapply

for licensure as the new business entity.

(I) A licensed manufacturer of an ignition interlock device shall maintain complete and accurate records for business conducted in the state of Ohio including:

(1) Testing certifications, protocols, results, and manuals for each device certified pursuant to rule 4501-45-04 of the Administrative Code,

(2) Certificate of product liability insurance, financial statements, and records for all certified devices sold, leased, or otherwise used in Ohio,

(3) Legal action pertaining to the licensed manufacturer.

(J) Records retained under this section shall be made available to the department within fifteen days of a written request by the department.

(K) Records shall be maintained for a period of not less than five years after the license expiration date and be made available to the department upon request.

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 a felony conviction, an operating a vehicle while intoxicated or drug related conviction, regardless of when or where the conviction occurred, a parole/probation violation, or a conviction for any crime involving dishonesty, deceit, or fraud.~~ 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 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.
- (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.
- (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 ~~which~~ 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 57, No. 67 of the Federal Register on April 7, 1992 (57 F.R. 11772, 1992)~~ 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 variable intervals ranging from ten to forty-five 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 0.25 g/dL, 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) On or before October 1, 2016, all certified ignition interlock devices for lease, sale, or other use in the state of Ohio, must be compliant with this paragraph.

(2) A complete quality assurance plan in accordance with appendix A of the NHTSA standards referenced in paragraph (D)(1) of this rule.

~~(2)~~(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, or following any change to ignition interlock device functionality. The testing protocol, and results, shall be reviewed and approved by the director of health;

~~(3)~~(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 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, ~~which~~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](#).

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 ~~shall~~[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 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.

4501-45-05

Denial, suspension or revocation of licensing or certification.

- (A) The department shall deny the application for licensing filed by a manufacturer of an ignition interlock device, if the manufacturer fails to comply with all requirements set forth in sections 4510.43 and 4510.45 of the Revised Code, the rules set forth in this chapter, and for any reason(s) set forth in this rule.
- (B) The director shall deny the application for certification filed by a manufacturer of an immobilizing or disabling device, other than an ignition interlock device, and the application for certification filed by a manufacturer of an ignition interlock device, if the manufacturer fails to comply with all requirements set forth in sections 4510.43 and 4510.45 of the Revised Code, the rules set forth in this chapter, and for any of the reasons set forth in this rule.
- (C) The director shall suspend or revoke the license and/or certification(s) granted to a manufacturer of an ignition interlock device if the manufacturer fails to comply with all requirements set forth in sections 4510.43 and 4510.45 of the Revised Code, the rules set forth in this chapter, and for any of the reasons set forth in this rule.

If the director suspends or revokes a manufacturer's license and/or certification(s), 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 [as listed in paragraph \(F\) of rule 4501-45-11](#).

- (D) Reasons for denial, suspension, or revocation of a license or certification include, but are not limited to the following:
 - (1) The manufacturer filed an incomplete application for licensing, an incomplete application for certification, and/or failed to file all documents required by the application and the rules of this chapter;
 - (2) The application for licensing, and/or application for certification, was not accompanied by the required application fee at the time of filing;
 - (3) The manufacturer provided incorrect or erroneous information in an application filed with the department in order to obtain a license, in an application filed with the director in order to obtain certification of an immobilizing or disabling device, or in an application filed with the director in order to obtain certification of an ignition interlock device;
 - (4) A manufacturer's owner(s), officers, partners, agents, employees, contractors, or installers assisted or provided information that would enable a person

utilizing an ignition interlock device or immobilizing or disabling device to circumvent or tamper with the certified device installed in the person's motor vehicle;

- (5) The manufacturer voluntarily requests, in writing, that the director suspend or revoke its license or certification(s);
- (6) The manufacturer modified any aspect of its certified ignition interlock device or immobilizing or disabling device, and the director determines that the manufacturer must file a new application for certification;
- (7) The license application filed by the manufacturer is a renewal application, and the manufacturer failed to file its annual report and/or pay the total annual report fee as required by paragraph (F) of rule 4501-45-03 of the Administrative Code;
- (8) The manufacturer failed to timely pay all assessment(s) and/or penalties imposed by the director pursuant to rules 4501-45-07 and 4501-45-08 of the Administrative Code;
- (9) A manufacturer failed to comply with the requirements set forth in paragraph (D)(2) and paragraphs (G) to (I) of rule 4501-45-02 of the Administrative Code, [paragraph \(J\) of rule 4501-45-03 of the Administrative Code](#), or paragraphs (D)(3), (H), and (I) of rule 4501-45-04 of the Administrative Code.

4501-45-06

Appeals.

A manufacturer, whose original or renewal application for licensing is denied by the department, may appeal the decision to the director. The manufacturer shall serve the director with its notice of appeal, by certified mail, return receipt, not later than fourteen days after the date stated on the department's written notice of denial. If the manufacturer fails to timely file its notice of appeal within the fourteen day time period, the department's denial of a license shall become final.

The director shall appoint a hearing officer to preside over the hearing. The hearing officer shall schedule a hearing on the matter not later than thirty days after the date the director was served with the manufacturer's notice of appeal. The hearing officer may postpone or continue the hearing at the written request of the manufacturer, the director, or upon his/her own motion.

Following the hearing, the hearing officer shall prepare a written report setting forth findings of fact and a recommendation whether the director should uphold or reverse the department's denial of a license. The manufacturer shall be served with a copy of the hearing officer's written report by certified mail, return receipt.

If the director reverses the department's denial of a manufacturer's application for licensing, the director shall issue a written order directing the department to issue a license to the manufacturer.

If the director upholds the department's denial of a license, the manufacturer may file an appeal with the Franklin county common pleas court, stating with specificity, the grounds for such appeal. The manufacturer shall file its appeal with the court not later than ~~thirty~~ fifteen days after the date of mailing to the manufacturer ~~was served~~ with the hearing officer's written report. A copy of the manufacturer's appeal shall be served upon the director by certified mail, return receipt, postmarked on the date the manufacturer files its appeal with the court. ~~The decision of the Franklin county common pleas court shall be the final determination of the matter.~~

4501-45-07

Penalties for failure to timely file an annual report and/or pay the annual report fee.

- (A) The director shall charge a penalty against a manufacturer who fails to timely file an accurate annual report and/or pay the total annual report fee due, within the time period set forth in paragraph (F) of rule 4501-45-03 of the Administrative Code. The director shall charge a separate penalty against the manufacturer for each violation.
- (1) A manufacturer who fails to timely file an accurate annual report shall be charged a penalty in an amount not exceeding the greater of fifty dollars or ten per cent of the total annual report fee due. If the manufacturer fails to file an accurate annual report within sixty days following the date the annual report was due, the manufacturer may be subject to an assessment set forth in rule 4501-45-08 of the Administrative Code.
- (2) A manufacturer who fails to timely pay the total annual report fee due shall be charged a penalty in an amount not exceeding the greater of fifty dollars or ten percent of the total annual report fee due. If the manufacturer fails to pay its total annual report fee within sixty days following the date the annual report fee was due, the manufacturer may be subject to an assessment set forth in rule 4501-45-08 of the Administrative Code.
- (B) The director shall serve the notice of penalty(s) upon a manufacturer by certified mail, return receipt, at the address stated in the manufacturer's application for licensing. In the notice, the director shall state the basis and the amount of the penalty(s). Penalty(s) shall be paid in full within sixty days of the date of notice.
- (C) Any portion of the penalty(s) not paid in full by a manufacturer within sixty days of the date of notice, shall accrue interest at the rate per annum prescribed by section 5703.47 of the Revised Code, until the penalty(s) is/are paid in full. The director may take any action under Ohio law necessary to secure a judgment against the manufacturer for all outstanding monies owed.

4501-45-08

Assessments for failure to file accurate annual report and/or pay total annual report fee.

- (A) The director may make an assessment against a manufacturer who fails to file an accurate annual report, and/or pay the total annual report fee due, as set forth in division (B) of section 4510.45 of the Revised Code, within sixty days following the time period set forth in paragraph (F) of rule 4501-45-03 of the Administrative Code. The director may make a separate assessment against the manufacturer for each violation.
- (1) If a manufacturer fails to file an accurate annual report within sixty days following the time period set forth in paragraph (F) of rule 4501-45-03 of the Administrative Code, the manufacturer may be assessed fifty dollars per day from the date its annual report was due to be filed, up to and including the date the manufacturer files its annual report with the department. This assessment shall not exceed three thousand dollars.
 - (2) If a manufacturer fails to pay the total annual report fee within sixty days following the time period set forth in paragraph (F) of rule 4501-45-03 of the Administrative Code, the manufacturer may be assessed fifty dollars per day from the date its annual report fee was due to be paid, up to and including the date the manufacturer pays its annual report fee to the department. This assessment shall not exceed three thousand dollars.
 - (3) If the director possesses information, at any time, that indicates the correct total annual report fee due exceeds the amount the manufacturer paid, the director may audit the manufacturer's records to ascertain the correct total annual report fee due. Based upon the audit, the manufacturer shall be required to pay the difference found to be due, and in addition, the director may issue an assessment against the manufacturer of fifteen per cent of that difference. This assessment shall be separate from any assessment(s) imposed pursuant to paragraphs (A)(1) and (A)(2) of this rule.
- (B) The director shall serve a notice of assessment(s) upon a manufacturer by certified mail, return receipt, at the address stated in the manufacturer's application for licensing. In the notice, the director shall state the basis and the amount of the assessment(s), and shall provide instructions to the manufacturer on the manner in which to file a petition for reassessment.
- (C) If a manufacturer chooses to file a petition for reassessment, the manufacturer shall file its petition with the Franklin county common pleas court not later than ~~thirty~~ fifteen days after the date of mailing to the manufacturer ~~was served~~ with the notice of assessment(s). The manufacturer shall serve a file stamped copy of its petition for reassessment upon the director by certified mail, return receipt, postmarked on the date the manufacturer files its petition for reassessment with the court. In its

petition, the manufacturer shall state, with specificity, its objections to the assessment(s).

~~(D) The decision of the Franklin county common pleas court shall be the final determination of the matter.~~

~~(E)~~(D) If the manufacturer fails to file a petition for reassessment with the Franklin county common pleas court within the ~~thirty~~ fifteen day period as set forth in paragraph (C) of this rule, the assessment(s) shall become final and shall be paid within sixty days of the date the manufacturer was served with the notice.

~~(E)~~(E) Any portion of the assessment(s), or the difference found to be due in a manufacturer's annual report fee, not paid in full by the manufacturer within the sixty day period, shall accrue interest at the rate per annum prescribed by section 5703.47 of the Revised Code, until the assessment(s) and/or fee are paid in full. The director may take any action under Ohio law necessary to secure a judgment against the manufacturer for all outstanding monies owed.

4501-45-09

Warning labels for certified immobilizing or disabling devices.

- (A) A warning label shall be affixed to each certified immobilizing or disabling device, including an ignition interlock device, upon installation in a motor vehicle. The label shall state: "ANY PERSON TAMPERING, CIRCUMVENTING, OR OTHERWISE MISUSING THIS DEVICE IS SUBJECT TO A FINE, IMPRISONMENT, OR BOTH, AND MAY BE SUBJECT TO CIVIL LIABILITY."

- (B) The warning label shall be printed in boldface, capital letters, and the label shall be no smaller than one and one-half inches high and two inches long. The label shall be conspicuously affixed upon the front of each certified immobilizing or disabling device, including an ignition interlock device.

4501-45-10

Audits and inspections.

Pursuant to section 5502.011 of the Revised Code, each manufacturer of a certified immobilizing or disabling device, including a certified ignition interlock device, shall be subject to unannounced audits and inspections by the department of all records pertaining to each immobilizing or disabling device, and/or ignition interlock device, produced by the manufacturer. If sufficient cause exists, as determined by the director, that the manufacturer does not meet the requirements of any applicable laws or the rules of this chapter, the manufacturer's license and/or certification(s) of all immobilizing or disabling devices, and/or ignition interlock devices, shall be subject to immediate suspension or revocation by the director.

[A manufacturer shall retain every document related to device installation, operation, lease, sale, or any other use for five years.](#)

The director shall notify a manufacturer by certified mail, return receipt, if the director decides to suspend or revoke a manufacturer's license and/or suspend or revoke a manufacturer's certification(s) of an immobilizing or disabling device, and/or an ignition interlock device. The director's notice shall explain the reason(s) for such action.

If a manufacturer's license and/or a manufacturer's certification(s) is suspended or revoked pursuant to this rule, 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 [as listed in paragraph \(F\) of rule 4501-45-11.](#)

4501-45-11

Incorporated by reference.

Incorporated by reference. This chapter includes material that has been incorporated by reference. If the material is subject to change, only the specific version listed in this rule is incorporated. Any revision to the referenced material is not incorporated unless and until this rule has been amended to specify the new date.

(A) "ISO 17025" (May 2005) International Organization for Standardization. These documents are available for purchase at www.iso.org. ISO documents are also generally available at local public libraries and "The State Library of Ohio."

(B) "Application for Certification for Immobilizing or Disabling Devices other than ignition Interlock Devices" (October 2015) is made available to ignition interlock manufacturers and may be accessed via the Ohio department of public safety website at <http://ohiohighwaysafetyoffice.ohio.gov/index.stm#tog>.

(C) "Ignition Interlock Manufacturer Application for Licensing" (September 2015) is made available to ignition interlock manufacturers and may be accessed via the Ohio department of public safety website at <http://www.publicsafety.ohio.gov/links/OTS0030.pdf>.

(D) "Ignition Interlock Manufacturer Application for Certification" (October 2015) is made available to ignition interlock manufacturers and may be accessed via the Ohio department of public safety website at <http://www.publicsafety.ohio.gov/links/OTS0029.pdf>.

(E) "Ignition Interlock Licensing, Certification, and Annual Report Payment Processing" (September 2015) is made available to ignition interlock manufacturers and may be accessed via the Ohio department of public safety website at <http://www.publicsafety.ohio.gov/links/OTS0028.pdf>.

(F) "IGNITION INTERLOCK DEVICES CERTIFIED FOR USE IN OHIO" is made available and may be accessed via the Ohio department of public safety website at [http://www.publicsafety.ohio.gov/links/Approved Interlock Devices.pdf](http://www.publicsafety.ohio.gov/links/Approved%20Interlock%20Devices.pdf).