



# Common Sense Initiative

Mike DeWine, Governor  
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## Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Public Safety, Ohio Traffic Safety Office

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Regulation/Package Title (a general description of the rules' substantive content):

Ignition Interlock Devices

Rule Number(s): 4501-45-01 through 4501-45-11

Date of Submission for CSI Review: 9/14/2023

Public Comment Period End Date: 09/28/2023 (Extended to 10/05/2023)

**Rule Type/Number of Rules:**

New/\_\_\_ rules

No Change/\_\_\_ rules (FYR? )

Amended/ 11 rules (FYR? 11)

Rescinded/\_\_\_ rules (FYR? \_\_\_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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### **Reason for Submission**

1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.
- c. ☒ Requires specific expenditures or the report of information as a condition of compliance.
- d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

### **Regulatory Intent**

2. Please briefly describe the draft regulation in plain language.

*Please include the key provisions of the regulation as well as any proposed amendments.*

Chapter 4501-45 of the Administrative Code sets forth the requirements for manufacturers to become licensed and have their ignition interlock devices certified. The proposed revisions are to update current and best practices.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

Revised Code Sections 4510.43 and 4510.45.

4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

*If yes, please briefly explain the source and substance of the federal requirement.*

No.

5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

N/A.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The purpose of the regulation is to fulfill the statutory obligation under R.C. 4510.43 and R.C. 4510.45 to license manufacturers of ignition interlock devices prior to their engaging in business in Ohio and ensure that all devices for use in Ohio meet minimum acceptable performance standards as published by NHTSA.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The Department will continue to review applications for licensure and certification to ensure compliance. Evaluation of these documents will check for completeness and accuracy. Each model type must be tested by an independent testing laboratory and these results will be assessed to ensure all devices meet minimum standards.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

### **Development of the Regulation**

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The following stakeholders were emailed initial drafts of rule amendments on 6/28/2023: #1A Lifesaver, 1A Smart Start, A&A Product Company, Alcohol Detection Systems, Alcolock, B.E.S.T. Labs, Intoxalock, LowCost Interlock, RoadGuard Interlock, and SkyFine USA.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

Various grammatical and structural changes were made as suggested, in addition...Smart Start, LifeSafer, Alcolock, and Intoxalock provided stakeholder feedback as listed below:

#### Smart Start

Rule 4501-45-01 Paragraph (H)- adding language that a immobilizing or disabling device (separate of an interlock device) “shall not be cable of measure blood alcohol concentration (BAC).” This change has been made.

Rule 4501-45-02 Paragraph (A)- requiring a manufacturer of an immobilizing or disabling device to annually obtain certification. This change was not made, as Ohio Revised code section 4510.43 (A)(2) requires only ignition interlock devices to be certified annually.

Rule 4501-45-04 (D)(1)(a)(v)- Requested to change calibration period from 37 to 67. This change has been made from 37 to 67 days, but only if real time reporting is enabled.

Rule 4501-45-04 (D)(1)(c)- require that original application for certification “must include long term calibration stability testing...” This change was not made as it would mean all currently certified devices would need to be retested for long term calibration stability, thereby costing all manufacturers a testing fee for all devices.

Rule 4501-45-04 (I)- Limit to physical material modifications for notification, and proof that the modifications do not adversely affect the ability of the device to complete its purpose. Rule changed to allow the director to request a copy of the testing protocol instead of automatically requiring it.

Rule 4501-45-04 (S)- asked to eliminate 37 day requirement in favor of 67 days. The rule has already been modified allow for longer calibration and service calls only if the device employs real time reporting.

#### Life Safer

Rule 4501-45-02 (E)(1)- Noted that the Department does not currently list immobilizing or disabling device on the website. There is currently no list to publish as there currently are no licensed immobilizing or disabling devices.

Rule 4501-45-03 (D)- asked if licensing expiring in January to September 2024 be extended until the October-December deadline. A grace period will be applied until the new licensing period commences.

Rule 4501-45-04 (I)(2)- Stated it does not make sense to require new testing for most minor updates. Rule was changed to allow the director to request a copy of the testing protocol instead of automatically requiring it.

Rule 4501-45-05- Stated concern with no limit on how far back the criminal history reviews for the offense must encompass. Look back period of five years for misdemeanors and ten years for felonies added for convictions that do not involve a violent offense, sexually-oriented offense, child-related violent offense, or terrorism-related offense.

#### Intoxalock

4501-45-01 (E and M)- Stated that the terms “disqualifying offense” and “offense” are duplicative and “offense” should be removed. “Offense” is the term used in in Chapter 4510 of the Revised Code, and “Disqualifying offense” is used in Section 9.79 of the Revised Code, so both terms are needed.

4501-45-01 (H) -Suggested language to make clear immobilizing or disabling device does not include an ignition interlock device. As ignition interlock device has its own definition in the rule, it is already defined what it includes. Language was added to make it clear that an

immobilizing or disabling device does include an ignition blocking device and spells out its parameters.

4501-45-02 (Tagline)- Suggested removing “other than ignition interlock devices” from the title/tagline. This change has been made.

4501-45-02 (D and F)- Suggested that forms need to be updated based on update of definitions. Reference to form has been changed in the rule. The updated form will be put into circulation when the rule goes into effect.

4501-45-03 (C)- Suggested that a manufacturer of an ignition interlock device “ may” not be eligible for a license if the manufacturer certain parties of the manufacturer have been convicted of crimes listed in paragraph (C)(10) of rule 4501-45-05. Language was cleaned up but the word “may” was not used as it is ambiguous. Additionally suggested that that disqualifying offense for the manufacturer be limited to employees “who currently work for the manufacturer in the state of Ohio...” This change is not recommended as a majority of those represented by the rule are not Ohio residents.

4501-45-04 (C)- Suggested that that disqualifying offense for the manufacturer be limited to employees “who currently work for the manufacturer in the state of Ohio...” This change is not recommended as a majority of those represented by the rule are not Ohio residents.

4501-45-04 (D)(1)(a)- Stated that “These standards require” is confusing due to possible difference with NHSTA standards. Language changed to “These specifications must include.”

4501-45-04 (D)(1)(a)(i)- Expressed concern in the phrase “unlimited samples” as well as what to do if six minutes pass and no passing sample has been provided. The rule language was changed to specify how many time a retest can be required within one hour, and what happens if a retest is missed or failed within the six minute window. The Department of Public Safety does not agree with adding a reset or lockout countdown to the device as it is up to the courts to determine penalization for a violation, not the Department of Public Safety or the manufacturer.

4501-45-04 (D)(1)(a)(iii)- Asked for clarification that the BrAC set point is used for and IID and the not the alcohol reference value for calibration/accuracy check. The language was changed to make this clarification.

4501-45-04 (D)(1)(a)(iv)- Recommended language change to require the “...device contain a digital image capture device or camera...”, instead of “digital image identification device.” The language was changed to make this clarification.

4501-45-04 (O)- Recommended the allowance of a visual review of each installation site as an alternative to the onsite review. The Department of Public Safety believes that each manufacturer should have an onsite presence to deal with issues arising with service centers that cannot be solved via electronic methods to ensure compliance with state regulations.

4501-45-05(C)(10)- Stated concern with no limit on how far back the criminal history reviews for the offense must encompass. Look back period of five years for misdemeanors

and ten years for felonies added for convictions that do not involve a violent offense, sexually-oriented offense, child-related violent offense, or terrorism-related offense.

#### AlcoLock

4501-45-01 (F)- Recommended adding a blocking function to the ignition interlock device when connected to a hybrid or electric vehicle. This change was not made, but a definition for “ignition system” was added to alleviate this concern.

Additionally recommended that the measurement of concentration of alcohol in a person’s breath in gram of alcohol per 210 liters of breath. This change was made.

4501-45-01 (P)- Recommended to use term “service provider” or “authorized service provider. No change made here as this definition of “purchaser” is dealing with the role of the “customer” role.

4501-45-01 (Q)- Recommended to use the term “retest” unmodified to define the function of “rolling retest.” Change made as requested.

4501-45-04 (D)(1)(a)- Stated that “These standards require”, may be different than NHSTA model specifications. Language changed to “These specifications must include.”

4501-45-04 (D)(1)(a)(i)- Suggested use of retest. Change made as requested.

4501-45-04 (D)(1)(a)(iii)- Suggested change to be consistent with NHTSA model specifications. Change made as requested.

4501-45-04 (D)(1)(a)(iv)- Recommended language change to make intent clear on the use of a digital image capture/camera in the device. The language was changed to make this clarification.

4501-45-11- Suggested correcting reference to ISO/IEC 17025:2017. This change was not made as the reference is the overall documents and all version rather than once specific paragraph.

#### **11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

It is up to the judicial system to assign when an ignition interlock device is appropriate for an individual. However, the Department will keep records of information on the number of devices installed, repeat offenders, and other applicable information that would be available for continued analysis of the program.

#### **12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn’t the Agency consider regulatory alternatives? *Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

The statute does not provide for alternatives as they apply to manufacturer licensing. In regards to device certification, the Department and participating stakeholders agree that NHTSA provides the recognized and accepted standard for the industry, and therefore, no other alternatives for performance standards were considered.

**13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

The applicable sections of the Ohio Revised Code (4510.43 and 4510.45) and the Administrative Code (4501-45-01 thru 4501-45-11) were reviewed to ensure that these regulations do not conflict with or duplicate regulations governing ignition interlock manufacturer licensure and subsequent certification of the manufacturer's devices. Additionally, RegExplorer was used to do a complete sweep for regulations dealing with ignition interlock.

**14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The Department will continue to review applications for accuracy and completeness. As the regulation of the device standards is measurable and tested by independent laboratories, this ensures there is a consistent and predictable regulation as to whether or not a device meets accepted standards. The Department is developing training for inspections and working with the ignition interlock device industry to ensure that the public is protected through the proper use of the devices with as little impact to the business side of the industry as possible.

**Adverse Impact to Business**

**15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**

**a. Identify the scope of the impacted business community, and**

The regulations impact 11 currently licensed ignition interlock manufacturers in Ohio who have a combined 24 certified devices, as well 160 installer vendors, which is expected to rise.

**b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.*

In accordance with R.C. 4510.43 each immobilization and disabling device for application has an application fee and R.C. 4510.45 requires manufacturers of ignition interlock devices to apply for licensure and file an annual report, which both have applicable fees. It is expected that a manufacturer may have an adverse impact in the form of application fees, background checks, laboratory analyses, assessment and



potential penalties associated with annual report. Manufacturers may also be subject to penalties for failure to timely and accurately file annual reports and/or pay annual fees. Additionally, failure to timely and accurately file and/or pay annual fees shall be reasons for denial, suspension, or revocation of a license or certification.

Most of the fees associated with these regulations are set in statute. Annual application fees are \$100 for licensure and \$100 for each device to be certified. The annual report fee is 5% of net profit the manufacturer earned during the 12 months their license was valid. The time reported to compile this paperwork was several hours over the course of two days. To meet compliance with the updated standards, two of the responding manufacturers reported it could cost them anywhere from several thousand dollars up to \$50,000 and take 6 weeks to 7 months to update their devices to the updated standards. This would be a one-time cost unless the manufacturer changes the devices and requires them to be tested by an independent laboratory. Many manufacturers have already completed the new standards testing as other states have already adopted the new standards. Failure to timely file an annual report and/or pay the annual fee shall result in a penalty amount not exceeding the greater of \$50 or 10% of the annual report fee. Failure to file annual report or pay total annual report fee, may result in manufacturer being assessed \$50 per day up \$3,000 after 60 days of not filing/paying total annual report fee. The background check cost is approximately \$60 for state and federal, price varies depending on the agency that performs the check.

Background check fees include approximately \$35-60 for state and federal checks, the price varies depending on the agency that performs the check. The background check has been a requirement in the past, the method has been updated to current standards and will be a requirement instead of by request. The background checks are proposed to keep at-risk persons from becoming installers as the devices being installed are there to provide for the safety of the public by keeping intoxicated persons off the road.

**16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).**

Several instances where the manufacturer etc.... must notify the Department of something have been eliminated. Reduction in the regulatory burden of the license and certification renewal process, i.e. less paperwork to submit and all will be on the same renewal schedule yearly. Certified mail requirement have been removed. Eliminated the requirement that background checks are submitted to the Department every three years for installers. Eliminated the requirement that new testing be submitted for device changes, instead it is now up to the director's discretion as to whether or not testing is needed. Eliminated the requirement that petitions for reassessments and requests for hearing be completed through the Franklin County Common Pleas Court.) Additionally the restriction count in the chapter has been reduced by approximately 60 restrictions.



**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The Department determined that the adverse impact is justified to ensure a standard level of service and performance to those who must ultimately use an immobilizing or disabling device in their vehicles.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

The authorizing statutes for manufacture license and device certification do not provide any exemptions or alternative means of compliance.

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

The Department will enforce all rules under 4510.43 and 4510.45. For licensees who may have incomplete or erroneous information in applications, they will be reviewed and advised of potential errors and procedures to correct errors. Failure to timely and/or accurately file annual reports may result in fines as well as denial, suspension, or revocation of license or certification. These rules have been adopted to ensure that the Department is able to work with the industry to avoid revocation while still addressing violations, and thus creating a more severe adverse impact.

**20. What resources are available to assist small businesses with compliance of the regulation?**

Notices of rule adoption will be sent to listed contacts for each manufacturer. A link to the Ohio Administrative Code will be added to the list of certified devices that is on the Department of Public Safety homepage:  
[http://www.publicsafety.ohio.gov/links/Approved\\_Interlock\\_Devices.pdf](http://www.publicsafety.ohio.gov/links/Approved_Interlock_Devices.pdf). Manufacturers will continue to be licensed and certified according to these specifications of the rules.