CSI - Ohio The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Public Safety	
Regulation/Package Title:	
Rule Number(s): Ohio Administrative Code 4501-45-01 thru 4501-45-11	
Date: 10/2/2015	
Rule Type:	
X New	X 5-Year Review
□ Amended	□ Rescinded
X No Change	

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

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

In accordance with 4510.43 and 4510.45 of the Revised Code, following the rule review, OSP has determined that rules 4501-45-01 through 4501-45-10 remain necessary. Chapter 4501-45 sets forth the requirements for manufacturers to become licensed and have their

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devices certified. The addition of 4501-45-11 is to centralize the information for materials incorporated by reference.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Revised Code 4510.43 and Revised Code 4510.45

- 3. 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.
- 4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement. N/A.
- 5. 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. 4501.43 and R.C. 4501.43 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.
- 6. 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.

Development of the Regulation

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

Representatives of the Ohio Department of Health and Ohio Judicial Conference, as well as the following currently licensed manufacturers: Smart Start of Ohio, Intoxalock, Draeger Safety Diagnostics, Lifesafer, Alcohol Detection Systems, Best Labs, Alcohol Countermeasure Systems, and Guardian Interlock. Each representative was contacted by e-mail or letter for input initially on November 24, 2014 and again on December 12, 2014 for input responses to be given by January 2, 2015.

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

Stakeholders expressed support for updating to the 2013 NHTSA standards. Most further inquired about alcohol set-point levels associated with the revised rules. The alcohol set-point is the threshold of breath alcohol concentration at which a vehicle is prevented from starting.

- 9. 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? When NHTSA updated their standards for ignition interlock, they sought input from states and manufacturers. The collective input from these groups sought to improve ignition interlocks and increase uniformity of the devices' functionalities through these updated standards.
- 10. 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?

The statute does not provide for alternatives as they apply to manufacturer licensing. In regards to device certification, the Department and participating stakeholders agreed that *NHTSA*'s is the recognized and accepted standard for the industry, and therefore, no other alternatives for performance standards were considered. The standards for which Ignition Interlock Devices are laboratory tested and set-to was considered in updating to the National Highway Traffic Safety Administration (NHTSA) Standards from the 1992 version to NHTSA 2013 standard. It was determined that the NHTSA 2013 standards are better suited for current technological times. The update in standards allowed for improved specificity of device performance.

11. Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

No. There is currently no mechanism in place to measure outcomes. Rather the regulation is a prescriptive process of baseline requirements that the devices must meet or exceed when subjected to independent laboratory testing.

12. 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.

13. 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.

Adverse Impact to Business

- 14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:
 - **a.** Identify the scope of the impacted business community; The regulations impact eight currently licensed ignition interlock manufacturers in Ohio who have a combined 12 certified devices, as well as potential applicants.
 - b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

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.

c. Quantify the expected adverse impact from the regulation.

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.

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.

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

Participating stakeholders shared that the regulations pose only minimal impact and do not pose undue hardship. Therefore 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

16. 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.

17. 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 procedure to correct errors. Failure to timely and/or seemingly accurately file annual report may be subject to fines as well as denial, suspension, or revocation of license or certification.

18. 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.

Manufactures will continue to be licensed and certified according to these specifications of the rules.