

*Covered entity* means an entity that is listed within section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database.

*Covered outpatient drug* has the meaning set forth in section 1927(k) of the Social Security Act.

*Manufacturer* has the meaning set forth in section 1927(k) of the Social Security Act.

*National Drug Code (NDC)* has the meaning set forth in 42 CFR 447.502.

*Pharmaceutical Pricing Agreement (PPA)* means an agreement described in section 340B(a)(1) of the PHSA.

*Quarter* refers to a calendar quarter unless otherwise specified.

*Secretary* means the Secretary of the Department of Health and Human Services and any other officer of employee of the Department of Health and Human Services to whom the authority involved has been delegated.

*Wholesaler* has the meaning set forth in 42 U.S.C. 1396r-8(k)(11).

## Subpart B—340B Ceiling Price

### § 10.10 Ceiling price for a covered outpatient drug.

A manufacturer is required to calculate 340B ceiling prices for each covered outpatient drug, by National Drug Code (NDC) on a quarterly basis.

(a) *Calculation of 340B ceiling price.* The 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places. To ensure the final price is operational in the marketplace, HRSA then multiplies this amount by the drug's package size and case package size. HRSA will publish the 340B ceiling price rounded to two decimal places.

(b) *Exception.* When the ceiling price calculation in paragraph (a) of this section results in an amount less than \$0.01 the ceiling price will be \$0.01.

(c) *New drug price estimation.* A manufacturer must estimate the ceiling price for a new covered outpatient drug as of the date the drug is first available for sale and must provide HRSA an estimated ceiling price for each of the first three quarters the drug is available for sale. Beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in paragraph (a) of this section. A manufacturer must calculate the actual ceiling prices for the first three quarters and refund or credit any covered entity which purchased the covered outpatient drug at a price

greater than the calculated ceiling price. The refunds or credits for the first three quarters must be provided to covered entities by the end of the fourth quarter.

### § 10.11 Manufacturer civil monetary penalties.

(a) *General.* Any manufacturer with a pharmaceutical pricing agreement that knowingly and intentionally charges a covered entity more than the ceiling price, as defined in § 10.10, for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed \$5,000 for each instance of overcharging a covered entity, as defined in paragraph (b) of this section. This penalty will be imposed pursuant to the procedures at 42 CFR part 1003. Any civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA.

(b) *Instance of overcharging.* An instance of overcharging is any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug.

(1) Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent.

(2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer.

(3) An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases.

(4) An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to pricing data submitted to CMS result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.

(5) A manufacturer's failure to provide the 340B ceiling price is not considered an instance of overcharging when a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase. Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's refusal to sell or make drugs available at the 340B price

resulted in the covered entity purchasing at the non-340B price.

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## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

#### 49 CFR Part 393

[Docket No. FMCSA-2014-0428]

RIN 2126-AB67

### Parts and Accessories Necessary for Safe Operation: Federal Motor Vehicle Safety Standards Certification for Commercial Motor Vehicles Operated by United States-Domiciled Motor Carriers

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of Proposed Rulemaking (NPRM), request for comments.

**SUMMARY:** FMCSA proposes to amend the Federal Motor Carrier Safety Regulations (FMCSRs) by requiring United States-domiciled (U.S.-domiciled) motor carriers engaged in interstate commerce to use only commercial motor vehicles (CMV) that display a certification label affixed by the vehicle manufacturer or a U.S. Department of Transportation (DOT) Registered Importer, indicating that the vehicle satisfied all applicable Federal Motor Vehicle Safety Standards (FMVSS) in effect at the time of manufacture. If the certification label is missing, the motor carrier must obtain, and a driver upon demand present, a letter issued by the vehicle manufacturer stating that the vehicle met all applicable FMVSS in effect at the time of manufacture.

**DATES:** You may submit comments by August 3, 2015.

**ADDRESSES:** Comments to the rulemaking docket should refer to Docket ID Number FMCSA-2014-0428 or RIN 2126-AB67, and be submitted to the Administrator, Federal Motor Carrier Safety Administration using any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>.
- *Fax:* 1-202-493-2251.
- *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

• *Hand Delivery*: Ground Floor, Room W12–140, DOT Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m. e.t., Monday through Friday, except Federal holidays.

To avoid duplication, please use only one of these four methods. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Michael Huntley, Chief, Vehicle and Roadside Operations Division, Office of Policy, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001, by telephone at (202) 366–9209 or via email at [Michael.Huntley@dot.gov](mailto:Michael.Huntley@dot.gov). FMCSA office hours are from 9 a.m. to 5 p.m., e.t Monday through Friday, except Federal holidays. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

**SUPPLEMENTARY INFORMATION:**

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**I. Public Participation and Request for Comments**

FMCSA invites you to participate in this rulemaking by submitting comments and related materials.

*Submitting Comments*

If you submit a comment, please include the docket number for this rulemaking (FMCSA–2014–0428), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and click on the “Submit a Comment” box, which will then become highlighted in blue. In the “Document Type” drop down menu, select “Rules,” insert “FMCSA–2014–0428” in the “Keyword” box, and click

“Search.” When the new screen appears, click on “Submit a Comment” in the “Actions” column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period and may change this proposed rule based on your comments.

*Viewing Comments and Documents*

To view comments, as well as any documents mentioned in this preamble, go to <http://www.regulations.gov> and click on the “Read Comments” box in the upper right hand side of the screen. Then, in the “Keyword” box insert “FMCSA–2014–0428” and click “Search.” Next, click the “Open Docket Folder” in the “Actions” column. Finally, in the “Title” column, click on the document you would like to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

*Privacy Act*

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

**II. Executive Summary**

*Purpose and Summary of the Major Provisions*

The FMCSRs require that motor carriers operating CMVs in the U.S., including Mexico- and Canada-domiciled carriers, ensure that the vehicles are equipped with the applicable safety equipment and features specified in 49 CFR part 393, Parts and Accessories Necessary for Safe Operations, which includes cross references to safety equipment and features that must be installed at the time of production. The National Highway Traffic Safety Administration (NHTSA) requires vehicle

manufacturers to certify that the vehicles they produce for sale and use in the U.S. meet all applicable FMVSS in effect at the time of manufacture. In addition, they must affix an FMVSS certification label to each vehicle in accordance with the requirements of 49 CFR part 567. This NPRM would require U.S.-domiciled motor carriers engaged in interstate commerce to use only CMVs that display an FMVSS certification label affixed by the vehicle manufacturer indicating that the vehicle: (1) satisfied all applicable FMVSS in effect at the time of manufacture; or (2) has been modified to meet those standards and legally imported by a DOT Registered Importer. In the absence of such a label (*e.g.*, because of vehicle damage or deliberate removal), the motor carrier must obtain, and a driver upon demand present, a letter issued by the vehicle manufacturer stating that the vehicle satisfied all applicable FMVSS in effect on the date of manufacture. The manufacturer should be able to determine quickly whether the vehicle was built to comply with the FMVSS by comparing the vehicle identification number (VIN) to its production records.

In the event a vehicle does not display a certification label, motor carriers would be responsible for providing their drivers with a letter from the vehicle manufacturer to present to Federal or State enforcement officials upon request.

This proposed rule would address the National Transportation Safety Board’s (NTSB) concerns about the operation of CMVs that do not display certification labels. It would not apply to foreign-domiciled vehicles (*i.e.*, CMVs operated by Mexico- and Canada-domiciled motor carriers) engaged in international traffic, as regulations enforced by U.S. Customs and Border Protection permit such vehicles to be admitted to the U.S. without formal importation, payment of duty, or compliance with the FMVSS.<sup>1</sup>

*Benefits and Costs*

Generally, motor carriers engaging in interstate commerce with a principal place of business in the U.S. would not experience any regulatory burden as a result of this rulemaking unless the motor carrier: (1) had vehicles with missing certification labels; or (2) had acquired a vehicle that was not originally manufactured for sale or use

<sup>1</sup> The applicable Customs and Border Protection regulations governing instruments of international traffic are found in 19 CFR 10.41, 10.41a, and part 123, subpart B. With certain exceptions, instruments of international traffic may be released without entry or the payment of duty, subject to the provisions set forth in these regulations.

in this country that had somehow been improperly imported. The Agency lacks data on the prevalence of such vehicles in the fleets of U.S.-domiciled motor carriers. FMCSA seeks comment on: (1) the size of the CMV population originally certified as FMVSS-compliant that now lacks certification labels because of vehicle damage, deliberate removal, or other reasons; and (2) the number of CMVs operated by U.S.-domiciled carriers that lack certification labels because they were neither designed nor certified to be FMVSS-compliant. FMCSA believes that most missing labels fall into the first of these two categories.

This rulemaking is not intended to deprive motor carriers of the use of vehicles produced in compliance with the appropriate FMVSS, but rather to prevent vehicles not manufactured or modified to meet those standards from being operated by U.S.-domiciled interstate carriers.

FMCSA believes this rulemaking would have no impact on the vast majority of U.S. carriers. Because motor vehicles manufactured for sale or use in the U.S. must display an FMVSS certification label, and because vehicles that are properly imported by a Registered Importer must likewise display an FMVSS certification label, all vehicles operated by U.S. motor carriers would typically already have such labels. However, there may be circumstances where a CMV lacking an FMVSS certification label is used in interstate commerce by an American carrier. This NPRM would force the carrier to incur one-time costs to determine whether the label had simply been lost or, more seriously, whether the vehicle may have been improperly imported. In order to minimize those costs, FMCSA will accept as proof of compliance with the FMVSS a letter from the vehicle manufacturer stating that the subject vehicle satisfied all applicable FMVSS in effect at the time of manufacture. The Agency is unable to quantify the costs associated with this alternative demonstration of compliance, but expects them to be minimal. FMCSA seeks comment on the cost and effectiveness of this letter-based validation process when an FMVSS certification label is missing or too damaged to read.

With regard to benefits, the rule would make it easier for FMCSA and its State partners to identify CMVs operated by U.S.-domiciled motor carriers that may have been introduced into interstate commerce without the proper FMVSS certification.

In the absence of monetizable benefits, and due to uncertainty

regarding the size of the affected population and the costs to comply with this rulemaking, FMCSA proposes to use a threshold analysis to quantify the benefits necessary to offset the costs of the rule. This threshold analysis will be included in the final rule, drawing upon information provided in comments to the docket and other data to establish lower and upper bounds for costs. The Agency seeks comments on the value of a threshold analysis versus a qualitative assessment of the rule's potential impact.

### III. Legal Basis for the Rulemaking

This NPRM is based on the authority of the Motor Carrier Act of 1935 (1935 Act) and the Motor Carrier Safety Act of 1984 (MCSA or 1984 Act), both of which provide broad discretion to the Secretary of Transportation (Secretary) in implementing their provisions.

The 1935 Act provides that the Secretary may prescribe requirements for: (1) qualifications and maximum hours of service of employees of, and safety of operation and equipment of, a motor carrier [49 U.S.C. 31502(b)(1)]; and (2) qualifications and maximum hours of service of employees of, and standards of equipment of, a motor private carrier, when needed to promote safety of operation [49 U.S.C. 31502(b)(2)]. These proposed amendments are based on the Secretary's authority to regulate the safety and standards of equipment of for-hire and private motor carriers.

The 1984 Act gives the Secretary concurrent authority to regulate CMVs and the drivers and motor carriers that operate them, as well as the vehicles themselves [49 U.S.C. 31136(a)]. Section 31136(a) requires the Secretary to publish regulations on CMV safety. Specifically, the Act sets forth minimum safety standards to ensure that: (1) CMVs are maintained, equipped, loaded, and operated safely [49 U.S.C. 31136(a)(1)]; (2) the responsibilities imposed on operators of CMVs do not impair their ability to operate the vehicles safely [49 U.S.C. 31136(a)(2)]; (3) the physical condition of CMV operators is adequate to enable them to operate the vehicles safely [49 U.S.C. 31136(a)(3)]; and (4) the operation of CMVs does not have a deleterious effect on the physical condition of the operators [49 U.S.C. 31136(a)(4)]. Section 32911 of the Moving Ahead for Progress in the 21st Century Act (MAP-21) [Pub. L. 112-141, 126 Stat. 405, 818, July 6, 2012] enacted a fifth requirement, *i.e.*, that the regulations ensure that "(5) an operator of a commercial motor vehicle is not coerced by a motor carrier, shipper, receiver, or

transportation intermediary to operate a commercial motor vehicle in violation of a regulation promulgated under this section, or chapter 51 [Transportation of Hazardous Material] or chapter 313 [Commercial Motor Vehicle Operators] of this title" [49 U.S.C. 31136(a)(5)].

This proposed rule would prohibit U.S.-domiciled motor carriers from operating CMVs that are not appropriately labeled to document that they met all applicable FMVSS in effect at the time of manufacture. Motor carriers could continue to purchase foreign vehicles for importation into the United States, but NHTSA requires these vehicles to have documentation and labels to verify that they have been modified to comply with the applicable FMVSS. Because FMCSA has exercised its statutory authority to include cross-references to the FMVSS in the FMCSRs, this rulemaking is consistent with 49 U.S.C. 31136(a)(1). This proposed rule does not impact the responsibilities or physical condition of drivers as contemplated by 49 U.S.C. 31136(a)(2) and (3), respectively, and deals with 49 U.S.C. 31136(a)(4) only to the extent that a vehicle operated in accordance with the safety regulations is less likely to have a deleterious effect on the physical condition of a driver. Because both: (1) the number of vehicles operated by U.S.-domiciled motor carriers without an FMVSS certification label; and (2) the cost of demonstrating FMVSS compliance through a letter from the vehicle manufacturer, are expected to be small, the Agency believes that the number of drivers who might be coerced to operate CMVs that do not comply with this rule is *de minimis*, and may be zero. FMCSA has considered the costs and benefits of the rule, as required by 49 U.S.C. 31136(c)(2)(A) and 31502(d).

### IV. Background

Part 567 of title 49 of the Code of Federal Regulations (49 CFR part 567) requires that manufacturers of motor vehicles built for sale or use in the U.S. must affix a label certifying that the motor vehicle meets all applicable FMVSS in effect on the date of manufacture.<sup>2</sup> Part 567 provides detailed requirements concerning the location of and information to be displayed on the label. These requirements are applicable to manufacturers of CMVs produced for use in the U.S. The label must be affixed prior to the first sale of the CMV.

<sup>2</sup> These standards are codified in 49 CFR part 571. Most, but not all, of the FMVSS are cross-referenced in existing requirements of part 393.

The National Traffic and Motor Vehicle Safety Act (Vehicle Safety Act) (49 U.S.C. 30101, *et seq.*) expressly prohibits vehicles from being imported into the U.S. unless the vehicles—

(a) Comply with all applicable FMVSS in effect on the date of manufacture, and

(b) Bear a label certifying compliance with the FMVSS and applied to the vehicle either by a manufacturer at the time of manufacture or by a DOT Registered Importer after the vehicle has been brought into compliance.<sup>3</sup> This statutory requirement is currently codified at 49 U.S.C. 30112 and implemented in NHTSA's regulations codified at 49 CFR parts 567 and 571.

Under this proposal, all motor carriers operating in interstate commerce, including Mexico- and Canada-domiciled motor carriers, would continue to be responsible for complying with FMCSA's vehicle-related requirements in 49 CFR part 393, including the specific safety features and equipment mandated by the FMVSS and cross-referenced in part 393. Under FMCSA's Motor Carrier Safety Assistance Program, FMCSA and its State and local partners conduct more than 3 million roadside inspections each year on vehicles domiciled in the U.S., Mexico, and Canada operating in interstate commerce. Enforcement of the FMCSRs, and by extension the FMVSS they cross-reference, is the bedrock of these compliance activities, and helps ensure that all CMVs on U.S. highways are in safe and proper operating condition.

#### *National Transportation Safety Board Recommendations*

On December 8, 2009, the NTSB issued a series of recommendations to the Office of the Secretary of Transportation, FMCSA, and NHTSA concerning measures to ensure that CMVs operated in the U.S. are manufactured to comply with the applicable FMVSS. The recommendations were included in the NTSB's highway crash report titled "Motorcoach Rollover on U.S. Highway 59 near Victoria, Texas on January 2, 2008" (HAR-09/03/SUM, PB2009-916203). A copy of the report is

<sup>3</sup> An individual or business registered with NHTSA as an importer may import non-complying motor vehicles into the United States if NHTSA has determined that the vehicles are capable of being readily altered to comply with all applicable standards in effect at the time the vehicle is imported. The registered importer must provide the Federal Government with a bond at least equal to the dutiable value of the vehicle before it can be imported and must bring the vehicle into full compliance before the vehicle may be sold and the bond released.

included in the docket referenced at the beginning of this notice.

During its investigation of this crash, NTSB discovered that the motorcoach did not display an FMVSS certification label despite being registered in the U.S. While there is no indication that the absence of the FMVSS certification contributed to the crash, the NTSB noted the safety vulnerability of allowing vehicles without that certification to operate on the Nation's highways. This rulemaking would help to address the problem of U.S.-domiciled motor carriers acquiring and operating CMVs that were neither manufactured for sale nor modified for use in this country.

#### *Effect of the Certification Label Requirements on U.S.-Domiciled Motor Carrier Operations*

Generally, U.S.-domiciled motor carriers operating CMVs (as defined in 49 CFR 390.5) in interstate commerce have access to vehicles that were either originally manufactured domestically for use in the U.S. and have the required certification label, or were imported in accordance with the applicable NHTSA importation regulations. Imported vehicles must have the required label certifying the vehicle is in compliance with the applicable FMVSS. Therefore, most vehicles operated by U.S.-domiciled motor carriers should have certification labels that meet the requirements of 49 CFR part 567.<sup>4</sup>

#### *FMCSA's Safety Responsibility*

NHTSA and FMCSA have complementary responsibilities to ensure vehicle safety under their respective enabling legislation. NHTSA's responsibility generally covers the design and safety compliance testing of motor vehicles by manufacturers and others responsible for those activities. FMCSA's responsibility concerns the safe operation of CMVs in interstate commerce, and the regulatory compliance of motor carriers and drivers conducting such operations. Generally, enforcement of the FMCSRs by FMCSA and its State partners is accomplished through roadside inspections. Under current roadside

<sup>4</sup> The FMVSS and the certification label requirement are not applicable to vehicles or items of equipment manufactured for, and sold directly to, the Armed Forces of the United States in conformance with contract specifications (49 CFR 571.7). Therefore, when a motor carrier purchases surplus equipment from the Armed Forces for subsequent use in interstate commerce, the vehicle may not have a certification label. However, because the FMCSRs cross-reference most of the FMVSS, the motor carrier would be required to ensure that the vehicle was retrofitted to meet the referenced standards, as well as all applicable motor carrier regulations.

inspection enforcement procedures, if violations or deficiencies of the FMCSRs are serious enough to meet the current out-of-service criteria, the vehicle is prohibited from operating until the problems are corrected. The roadside inspection procedures are the same for all CMVs operated in the U.S., regardless of the motor carrier's country of domicile.

If FMCSA adopts the proposed rule, the Agency and its State partners would then be able to enforce the prohibition in 49 U.S.C. 30112 against the use or importation of non-compliant CMVs by citing U.S.-domiciled motor carriers that fail to display the required certification label. Enforcement action would be taken in a manner consistent with FMCSA's existing compliance policies and programs on vehicle-oriented regulations under 49 CFR part 393.<sup>5</sup> As it does with other violations of the FMCSRs, the Agency would compile data regarding uncertified vehicles and determine whether there are patterns of non-compliance by specific U.S.-domiciled interstate motor carriers.

#### **V. Discussion of the Proposed Rule**

FMCSA is proposing to amend the FMCSRs to require that U.S.-domiciled motor carriers ensure that their CMVs have a certification label affixed to the vehicle by the vehicle manufacturer or by a DOT Registered Importer that meets the requirements of 49 CFR part 567. If a CMV operated by a U.S.-domiciled motor carrier is missing the certification label because of vehicle damage, deliberate removal, or other reasons, the motor carrier must obtain, and a driver must upon demand present, a letter issued by the vehicle manufacturer stating that the vehicle satisfied all applicable FMVSS in effect at the time of manufacture. As explained above, U.S.-domiciled motor carriers typically would have access only to vehicles that meet the applicable FMVSS and display a certification label that meets the requirements of 49 CFR part 567. Therefore, FMCSA does not expect that motor carriers would have to change the way they operate to comply with the requirements proposed today. However, the proposed rule would require U.S.-domiciled motor carriers to maintain the label affixed by the manufacturer or DOT Registered Importer or other documentation that confirms the CMV was manufactured per the applicable

<sup>5</sup> In other words, failure to display a certification label could result in a citation and fine during a roadside inspection, or a civil penalty as a result of a compliance review. Under the current out-of-service criteria, it would not constitute grounds to place a vehicle out of service in the absence of vehicle defects meeting those criteria.

FMVSS. The Agency seeks comment on potential costs involved to replace the label in the instance of damage or other loss.

## VI. Regulatory Analyses

### *Executive Order 12866 (Regulatory Planning and Review and DOT Regulatory Policies and Procedures as Supplemented by E.O. 13563)*

FMCSA has determined that this proposed rule is not a significant regulatory action within the meaning of Executive Order (E.O.) 12866, as supplemented by E.O. 13563 (76 FR 3821, January 21, 2011), or within the meaning of DOT regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980; 44 FR 11034, February 2, 1979). The Agency believes the potential economic impact is negligible because vehicles manufactured for sale and use in the United States have FMVSS certification labels or can be confirmed as being FMVSS-compliant by the manufacturer through a comparison of the vehicle's VIN and the manufacturer's production records. While a U.S.-domiciled carrier may occasionally obtain a vehicle that does not have an FMVSS certification, the Agency believes this practice would occur less frequently under the proposed rule. As such, the costs of the rule would not begin to approach the \$100 million annual threshold for economic significance. Moreover, the Agency does not expect the rule to generate substantial congressional or public interest. This proposed rule therefore has not been formally reviewed by the Office of Management and Budget (OMB).

### *Regulatory Flexibility Act*

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires Federal agencies to consider the effects of the regulatory action on small business and other small entities and to minimize any significant economic impact. The term "small entities" comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and governmental jurisdictions with populations of less than 50,000. Accordingly, DOT policy requires an analysis of the impact of all regulations on small entities and mandates that agencies strive to lessen any adverse effects on these businesses.

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II, Pub. L. 104-121, 110 Stat. 857, March 29, 1996), FMCSA does not

expect the proposed rule to have a significant economic impact on a substantial number of small entities. For those entities affected by this proposed rule, in the absence of definitive data on the cost to demonstrate FMVSS compliance at the time of manufacture for an otherwise FMVSS-compliant vehicle, FMCSA assumes the cost is minimal and poses no disproportionate burden to small entities.

### *Assistance for Small Entities*

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996, FMCSA wants to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking initiative. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please consult the FMCSA point of contact listed in the **FOR FURTHER INFORMATION CONTACT** section of the proposed rule.

Small businesses may send comments on the actions of Federal employees who enforce or otherwise determine compliance with Federal regulations to the Small Business Administration's Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of FMCSA, call 1-888-REG-FAIR (1-888-734-3247). DOT has a policy ensuring the rights of small entities to regulatory enforcement fairness and an explicit policy against retaliation for exercising these rights.

### *Unfunded Mandates Reform Act of 1995*

This proposed rule would not impose an unfunded Federal mandate, as defined by the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532 *et seq.*), that would result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$151 million (which is the value of \$100 million in 2012 after adjusting for inflation) or more in any 1 year.

### *Executive Order 13132 (Federalism)*

A rule has Federalism implications if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on the States. FMCSA has analyzed this proposed rule under Executive Order

13132 and determined that it does not have Federalism implications.

### *Executive Order 12988 (Civil Justice Reform)*

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### *Executive Order 13045 (Protection of Children)*

E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, Apr. 23, 1997), requires agencies issuing "economically significant" rules, if the regulation also concerns an environmental health or safety risk that an agency has reason to believe may disproportionately affect children, to include an evaluation of the regulation's environmental health and safety effects on children. The Agency determined this proposed rule is not economically significant. Therefore, no analysis of the impacts on children is required. In any event, the Agency does not anticipate that this regulatory action could in any respect present an environmental or safety risk that could disproportionately affect children.

### *Executive Order 12630 (Taking of Private Property)*

FMCSA reviewed this notice of proposed rulemaking in accordance with Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights, and has determined it will not effect a taking of private property or otherwise have taking implications.

### *Privacy Impact Assessment*

Section 522 of title I of division H of the Consolidated Appropriations Act, 2005, enacted December 8, 2004 (Pub. L. 108-447, 118 Stat. 2809, 3268, 5 U.S.C. 552a note), requires the Agency to conduct a privacy impact assessment of a regulation that will affect the privacy of individuals. This rule does not require the collection of any personally identifiable information.

The Privacy Act (5 U.S.C. 552a) applies only to Federal agencies and any non-Federal agency that receives records contained in a system of records from a Federal agency for use in a matching program. FMCSA has determined this proposed rule will not result in a new or revised Privacy Act System of Records for FMCSA.

*Executive Order 12372  
(Intergovernmental Review)*

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this program.

*Paperwork Reduction Act*

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. FMCSA determined that no new information collection requirements are associated with this NPRM. The information collection requirements associated with FMVSS certification labels are covered by NHTSA under OMB Control Number 2127-0512, "Consolidated Labeling Requirements for Motor Vehicles (Except the VIN Numbers)."

*National Environmental Policy Act and Clean Air Act*

FMCSA analyzed this proposed rule in accordance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and determined under our environmental procedures Order 5610.1 (69 FR 9680, March 1, 2004) that this action does not have any effect on the quality of the environment. Therefore, this NPRM is categorically excluded (CE) from further analysis and documentation in an environmental assessment or environmental impact statement under FMCSA Order 5610.1, paragraph 6(b) of Appendix 2. The CE under paragraph 6(b) addresses rulemakings that make editorial or other minor amendments to existing FMCSA regulations. A Categorical Exclusion Determination is available for inspection or copying in the *Regulations.gov* Web site listed under **ADDRESSES**.

FMCSA also analyzed this proposed rule under the Clean Air Act, as amended (CAA), section 176(c) (42 U.S.C. 7401 *et seq.*), and implementing regulations promulgated by the Environmental Protection Agency. Approval of this action is exempt from the CAA's general conformity requirement since it does not affect direct or indirect emissions of criteria pollutants.

*Executive Order 12898 (Environmental Justice)*

Under E.O. 12898, each Federal agency must identify and address, as appropriate, "disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority

populations and low-income populations" in the United States, its possessions, and territories. FMCSA evaluated the environmental justice effects of this proposed rule in accordance with the E.O., and has determined that no environmental justice issue is associated with this proposed rule, nor is there any collective environmental impact that would result from its promulgation.

*Executive Order 13211 (Energy Supply, Distribution, or Use)*

FMCSA has analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. FMCSA has determined that it is not a "significant energy action" under that executive order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, this proposed rule does not require a Statement of Energy Effects under Executive Order 13211.

*Executive Order 13175 (Indian Tribal Governments)*

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

*National Technology Transfer and Advancement Act*

The National Technology Transfer and Advancement Act (15 U.S.C. 272 note) requires Federal agencies proposing to adopt technical standards to consider whether voluntary consensus standards are available. If the Agency chooses to adopt its own standards in place of existing voluntary consensus standards, it must explain its decision in a separate statement to OMB. Because this NPRM does not involve the adoption of FMCSA technical standards, there is no need to submit a separate statement to OMB on this matter.

*E-Government Act of 2002*

The E-Government Act of 2002, Public Law 107-347, section 208, 116 Stat. 2899, 2921 (Dec. 17, 2002), requires Federal agencies to conduct a privacy impact assessment for new or substantially changed technology that

collects, maintains, or disseminates information in an identifiable form. No new or substantially changed technology would collect, maintain, or disseminate information as a result of this proposed rule. As a result, FMCSA has not conducted a privacy impact assessment.

**List of Subjects in 49 CFR Part 393**

Highway safety, Motor carriers, Motor vehicle safety.

For the reasons stated above, FMCSA proposes to amend title 49, Code of Federal Regulations, chapter III, subchapter B part 393, as follows:

**PART 393—PARTS AND ACCESSORIES NECESSARY FOR SAFE OPERATION**

■ 1. The authority citation for part 393 continues to read as follows:

**Authority:** 49 U.S.C. 31136, 31151, and 31502; sec. 1041(b) of Pub. L. 102-240, 105 Stat. 1914, 1993 (1991); and 49 CFR 1.87.

■ 2. Add § 393.8 to subpart A to read as follows:

**§ 393.8 Federal Motor Vehicle Safety Standard Certification Labels.**

(a) Each commercial motor vehicle operated by a U.S.-domiciled motor carrier, as indicated by its principal place of business, must be built or modified to meet all applicable Federal Motor Vehicle Safety Standards (FMVSS) (codified in 49 CFR part 571). The requirements must be satisfied by:

(1) A label affixed by the vehicle manufacturer certifying that the vehicle was built to meet all applicable FMVSS in effect on the date of manufacture; or

(2) A label affixed by a DOT Registered Importer, as defined in 49 CFR part 592, certifying that the vehicle has been modified to conform to all applicable FMVSS in effect on the date of manufacture; or

(3) A letter issued by the vehicle manufacturer stating that the vehicle satisfied all applicable FMVSS in effect at the time of manufacture.

(b) The certification labels required by this section must comply with the requirements of 49 CFR part 567.

Issued under the authority of delegation in 49 CFR 1.87 on: May 27, 2015.

**T.F. Scott Darling, III,**

*Chief Counsel.*

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