

inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of these uses of the substances in table 1 because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing safety in our evaluation of this FAP. In addition to our consideration of this petition, we are considering information on the safety of many of the ortho-phthalates listed in table 1 as part of our consideration of a petition designated for reference as FAP 6B4815 (see 81 FR 31877, May 20, 2016).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(m) because the petition requests an action that would prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioner has stated that, to petitioner's knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 6, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-24657 Filed 11-13-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 23 CFR Parts 630 and 635

[FHWA Docket No. FHWA-2018-0036]

RIN 2125-AF84

#### Construction and Maintenance— Promoting Innovation in Use of Patented and Proprietary Products

**AGENCY:** Federal Highway Administration (FHWA), Department of Transportation (DOT).

**ACTION:** Notice of proposed rulemaking (NPRM); request for comments.

**SUMMARY:** This rulemaking would provide greater flexibility to States to use proprietary or patented materials in Federal-aid projects. The FHWA is

seeking comment on two alternate proposals to help advance this objective: First, FHWA proposes to amend and replace the requirements relating to patented and proprietary product approvals with a more flexible general requirement that enhances fairness, open competition, and transparency in the product selection process.

Alternatively, the agency proposes rescinding the requirements, thereby encouraging further innovation in the development of new highway transportation technology and methods, as well as potentially reducing costs.

**DATES:** Comments must be received on or before January 14, 2019. Late-filed comments will be considered to the extent practicable.

**ADDRESSES:** To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor Room W12-140, Washington, DC 20590;
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366-9329.

- *Instructions:* You must include the agency name and docket number or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comments. All comments received will be posted without change to [www.regulations.gov](http://www.regulations.gov), including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Mr. John Huyer, Office of Preconstruction, Construction and Pavements, (651) 291-6111 or, Mr. William Winne, Office of the Chief Counsel, (202) 366-1397, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

#### SUPPLEMENTARY INFORMATION:

##### Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at <http://www.regulations.gov>. Electronic submission and retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days a year. Please follow the

instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: <http://www.archives.gov/federal-register> and the Government Publishing Office's web page at: <http://www.gpo.gov/fdsys>.

#### Background

There are differing practices across the United States on whether government entities may specify a patented material, article, or process in the letting of public works contracts through competitive bidding.<sup>1</sup> Some jurisdictions prohibit the practice altogether on the grounds that it would inhibit competition, particularly where only one contractor can provide the specified material.<sup>2</sup> Other jurisdictions allow the specification as long as the use of any other article equally as suitable is also allowed.<sup>3</sup> The Federal government's regulations on direct procurement and the uniform regulations on Federal financial assistance take the latter approach.<sup>4</sup> In the majority of States, however, the practice of specifying a patented product in government contracts is allowed.<sup>5</sup>

The Federal-aid Road Act of 1916 (1916 Act)<sup>6</sup> was silent about patented and proprietary products but provided that Federal-aid funded State highway construction was "subject to the inspection and approval of the Secretary of Agriculture, and in accordance with the rules and regulation made pursuant to this Act."<sup>7</sup>

Accordingly, regulations implementing the 1916 Act were issued on September 1, 1916. Regulation 8, Section 4 of those rules provided, "No part of the money apportioned under the act shall be used, directly or indirectly, to pay, or to reimburse a State, county, or local subdivision for the payment of any premium or royalty on any patented or proprietary material, specification, process, or type of construction, unless purchased or obtained on open actual competitive bidding at the same or a less cost than

<sup>1</sup> See generally 10 McQuillin Mun. Corp. § 29.42 (3d ed.).

<sup>2</sup> Examples include Illinois, Indiana, Kentucky, Louisiana, Massachusetts, and Wisconsin.

<sup>3</sup> Examples include California, Iowa, New Jersey, and New York.

<sup>4</sup> See 48 CFR 52.211-6 and 2 CFR 200.319(a)(6).

<sup>5</sup> Examples include Arizona, Colorado, Connecticut, Florida, Idaho, Kansas, Maryland, Michigan, Montana, Nebraska, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, and Washington.

<sup>6</sup> 1916 Act, ch. 241, 39 Stat. 355.

<sup>7</sup> The Office of Public Roads was the predecessor agency of FHWA and was part of the Department of Agriculture in 1916.

unpatented articles or methods equally suitable for the same purpose.” This regulation connected competitive bidding and lower cost to the restriction on the specification of proprietary products in Federal-aid contracts and has been a requirement of the Federal-aid highway program since its issuance.

In the Federal Highway Act of 1938 (1938 Act), Congress established in statute a competition standard by requiring the Secretary to approve, in connection with federally aided State highway construction projects, “only such methods of bidding and such plans and specifications of highway construction . . . as will be effective in securing competition and conducive to safety, durability, and economy of maintenance.”<sup>8</sup> This legislation preceded the current statute codified at 23 U.S.C. 112(a).

During the debate related to the enactment of Section 13 of the 1938 Act, Congressman Whittington expressly tied the rule on proprietary products to the newly enacted statutory requirement for competitive bidding. “It says there shall be competitive bidding. This means that all types of roads conducive to safety, durability, and economy will be considered. This means that only plans, specifications, and methods that provide for competition will be approved. All will be given a square deal. No special method, no special material will be selected to the exclusion of other materials.”<sup>9</sup>

In 1954, Congress explicitly required competitive bidding, while also providing a public interest exception, when it mandated that federally funded State highway construction work be “performed by contract awarded by competitive bidding under such procedures as may by regulations be prescribed by the Secretary . . . unless the Secretary . . . shall affirmatively find that, under the circumstances related to a given project, some other method is in the public interest.”<sup>10</sup> This legislation preceded the current statute codified at 23 U.S.C. 112(b)(1).

Over the years, the regulation was clarified through various policy and guidance memoranda, and subsequent **Federal Register** Notices, including 25 FR 4162 published on May 11, 1960. The regulatory language has received only relatively minor changes since that time.

The current regulation at 23 CFR 635.411 seeks to promote competitive

bidding by prohibiting FHWA participation in the cost of patented or proprietary products or materials except when: (1) Such patented or proprietary item is purchased or obtained through competitive bidding with equally suitable unpatented items; (2) a State Department of Transportation (State DOT) certifies either that such patented or proprietary item is essential for synchronization with existing highway facilities, or that no equally suitable alternate exists; or (3) a patented or proprietary item is used for research or for a distinctive type of construction on relatively short sections of road for experimental purposes. In addition, and also under the current regulation, States may specify a material or product based on a showing of public interest. Without using one of the exceptions described above, the State DOT may choose to use a particular patented or proprietary product, but FHWA funds may not participate in its cost. Patented and proprietary products are used widely on Federal-aid projects, through competition and where State DOTs apply one of the exceptions provided in 23 CFR 635.411.

Many States have been delegated authority under 23 U.S.C. 106 to approve public interest findings without the direct involvement of FHWA. States retain the ability to apply the other exceptions (certification, research) provided under 23 CFR 635.411.

Following its promulgation shortly after the inception of the Federal-aid road program in 1916, and even with the availability of exceptions, various stakeholders have criticized the regulation in 23 CFR 635.411 and its predecessors. Since 2005, FHWA has received inquiries and some expressions of concern from public agencies and industry about the perceived negative impact of the patented and proprietary products requirements in 23 CFR 635.411 on the development and use of new materials, equipment, or methods. Some claim the regulation has resulted in the unintended consequence of prohibiting the specification of innovative products on Federal-aid projects because the products were patented or proprietary. Others claim the requirements of 23 CFR 635.411 were unclear, were not being implemented uniformly, and resulted in barriers to the use of innovation in material and product selection on highway projects.

On December 1, 2017, the American Road and Transportation Builders Association (ARTBA) submitted comments to the DOT’s **Federal Register** Notice soliciting Regulatory Review ideas (82 FR 45750, October 2, 2017)

(docket ID: DOT–OST–2017–0069–2774). On March 27, 2018, ARTBA submitted a Petition for Rulemaking to repeal the patented and proprietary materials requirements in 23 CFR 635.411. The ARTBA comments and Petition for Rulemaking are available for review on the docket for this rulemaking.

### General Discussion of the Proposed Action

Ensuring competition and requiring low bid contracting in the Federal-aid highway program remain statutory duties of the Secretary. Statutory text codified at 23 U.S.C. 112(a) provides, “the Secretary shall require such plans and specifications and such methods of bidding as shall be effective in securing competition.” The statute also mandates that the Secretary ensure Federal-aid projects are performed pursuant to a contract awarded through competitive bidding to the lowest responsible bidder under 23 U.S.C. 112(b)(1). The regulation at 23 CFR 635.411 was promulgated to implement the statutory requirement to secure competition.

The existing regulation could do more to provide States further opportunity to consider the use of innovative, proprietary, or patented materials in Federal-aid projects. The proposals contained in this NPRM would promote the benefits of innovation and new technology and afford the flexibility necessary to take advantage of technological advancements in highway transportation. Such added flexibility may also provide State DOTs an advantage by potentially obtaining highway materials or products at a lower price. Specifying a patented article in the solicitation materials may not, by itself, limit competition. Rather, this practice might encourage various bidders to offer lower prices in the competition to deliver needed materials and ultimately lead to a more cost effective use of Federal funds in the long-term.

The FHWA believes most State DOTs utilize new product evaluation processes and approved product lists that provide fair and transparent procedures for the evaluation, selection, and use of materials, including patented and proprietary products.

State DOTs are responsible for the effective and efficient use of Federal-aid funds, subject to the requirements of Federal law. The FHWA believes, absent the current Federal patented and proprietary products requirements, State DOTs may implement material selection procedures that ensure fair and open competition while allowing for, and encouraging, innovation. Nevertheless,

<sup>8</sup>Public Law 75–584, 12, 52 Stat. 633, 636 (1938).

<sup>9</sup>Daily Congressional Record, May 6, 1938, pp. 6383–6.

<sup>10</sup>Federal-aid Highway Act of 1954, Public Law 83–350, 17(a), 68 Stat. 70, 75 (1954).

the statutory requirements of 23 U.S.C. 112 for competition and competitive bidding continue to apply to Federal-aid assisted State contracts.

Over the past century, States have assumed greater responsibility for Federal-aid project approval and oversight. For example, States may assume responsibility for “design, plans, specifications, estimates, contract awards, and inspection of projects” on the National Highway System (NHS), including the Interstate System, pursuant to 23 U.S.C. 106(c)(1). For projects that are not on the NHS, the States have assumed responsibility for those activities unless doing so would be inappropriate under 23 U.S.C. 106(c)(2). Providing State DOTs greater flexibility in the selection of products and materials used in Federal-aid projects may also be consistent with the provisions of 23 U.S.C. 106(c).

Put in context, and pursuant to 23 U.S.C. 145, the Federal-aid highway program is a federally-assisted, State-administered program. To potentially reduce costs and allow greater flexibility for the States in considering innovative products or materials for use in Federal-aid projects, FHWA proposes to amend the requirements at 23 CFR 635.411 related to patented and proprietary product approval. The FHWA seeks comment on two proposals: (1) Amending section 635.411 to allow States to certify compliance with the fair and open competition requirements of 23 U.S.C. 112 in selecting materials in Federal-aid projects; or alternatively, (2) rescinding parts of section 635.411.

Neither proposal would alter any requirements in the Manual on Uniform Traffic Control Devices found in 23 CFR part 655, subpart F.

### Section-by-Section Discussion

#### *Option 1: State Certification and Procedural Requirements*

Under Option 1, the existing regulatory requirements of 23 CFR 635.411(a)–(e) are being proposed for removal. The FHWA proposes replacing them with general certification requirements in new paragraphs 23 CFR 635.411(a) and 23 CFR 630.112(c)(6) to ensure competition in the selection of materials and products. This change would require a State DOT to: (1) Implement procedures and specifications that provide for fair, open, and transparent competition awarded only by contract to the lowest responsive bid submitted by a responsible bidder pursuant to 23 U.S.C. 112; and (2) certify that it adheres to those procedures and specifications. As mentioned above, FHWA believes that

many States already have procedures in place that would comply with this proposed requirement. The requirement of 23 CFR 635.411(f) would be retained because it was implemented to fulfill the mandate of section 1525 of the Moving Ahead for Progress in the 21st Century Act (MAP–21). This section is not concerned with patented and proprietary products, but with material types for culverts and storm sewers.

#### *Option 2: Repeal of 23 CFR 635.411(a)–(e)*

Alternatively, FHWA proposes to rescind the current proprietary and patented materials requirements contained in current paragraphs (a) through (e) and change the title of section 635.411 to “Culvert and Storm Sewer Material Types.” Under its new title, the former paragraph (f) of section 635.411 would be retained to fulfill the mandate of section 1525 of MAP–21 for States to retain autonomy for the selection of culvert and storm sewer material types.

#### *Request for Comment*

The FHWA is seeking comment on these alternative proposals, including the potential effects of the alternative proposals for the patented and proprietary products rule. Therefore, comments are invited with respect to the following questions:

(1) What are the challenges in incorporating patented and proprietary products into projects under the current regulatory process?

(2) How does the current regulation hinder the incorporation of innovative or cost-effective safety and other products into projects?

(3) How does the current regulation hinder the incorporation of proprietary products into projects?

(4) How would the proposals support or deter deployment of innovative or cost-effective products on projects? Could the proposals result in any unintended consequences that might deter such deployment?

(5) How could the proposals to allow specification of patented and proprietary products be implemented consistent with existing competition and low bid requirements?

(6) If FHWA rescinds the rule, what standards should FHWA rely on to determine if a State’s specification of a patented or proprietary product violates the competition mandate in 23 U.S.C. 112? For example, should FHWA rely on the standard found in the Office of Management and Budget’s (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2

CFR 200.319(a)(6)? OMB’s regulations at Part 200 provide a governmentwide framework for grants management, and 2 CFR 200.319(a)(6) describes seven situations considered to be restrictive of competition.<sup>11</sup>

(7) What positive or negative consequences might result from implementation of the proposals? Could the proposals result in potential costs or cost savings? If so, please describe the costs or cost savings and provide data to support these estimates. What might be the effects of the proposals on transparency in the materials selection process?

(8) What positive or negative consequences might affect small businesses that do not have the same marketing resources as larger firms?

(9) What differences in effects and compliance, if any, could result from the two alternative proposals?

(10) What is the difference between the number of proprietary products used on State and Federal-funded projects?

(11) Do the States follow rules or processes on State-funded projects similar to the Federal process embodied in section 635.411?

### Rulemaking Analyses and Notices

*Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), Executive Order 13771 (Reducing Regulations and Controlling Regulatory Costs), and DOT Regulatory Policies and Procedures*

The FHWA has determined that this action would not be a significant regulatory action within the meaning of Executive Order (E.O.) 12866, and within the meaning of the U.S. Department of Transportation’s regulatory policies and procedures. This action complies with EOs 12866, 13563, and 13771 to improve regulation. The FHWA anticipates that the economic impact of this rulemaking would be minimal. The FHWA anticipates that the proposed rule would not adversely affect, in a material way, any sector of the economy. In addition, these changes would not interfere with any action

<sup>11</sup> The regulations at 2 CFR 200.319(a)(6) describes some situations considered to be restrictive of competition, including: (1) Placing unreasonable requirements on firms in order for them to qualify to do business; (2) requiring unnecessary experience and excessive bonding; (3) noncompetitive pricing practices between firms or between affiliated companies; (4) Noncompetitive contracts to consultants that are on retainer contracts; (5) organizational conflicts of interest; (6) specifying only a “brand name” product instead of allowing “an equal” product to be offered and describing the performance or other relevant requirements of the procurement; and (7) any arbitrary action in the procurement process.

taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Although FHWA has determined that this action would not be a significant regulatory action, this proposed rule is expected to be an E.O. 13771 deregulatory action. This proposal could generate cost savings that are applicable to offsetting the costs associated with other regulatory actions as required by E.O. 13771. The FHWA has determined the cost savings of both proposed options are nearly the same. These cost savings, measured in 2018 dollars, are expected to be \$313,848 per year.

The cost savings resulting from this proposed regulatory action result from reduced administrative burden associated with the efforts by the States and FHWA related to the existing methods for approving patented and proprietary materials.

Currently there are three methods available to approve specific patented and proprietary products for use on Federal aid highway construction projects:<sup>12</sup>

1. *Certification*: A certification is the written and signed statement of an appropriate contracting agency official certifying that a particular patented or proprietary product is either:

a. Necessary for synchronization with existing facilities; or

b. A unique product for which there is no equally suitable alternative.

2. *Experimental Products*: If a contracting agency requests to use a proprietary product for research or for a distinctive type of construction on a relatively short section of road for experimental purposes, it must submit an experimental product work plan for review and approval. The work plan should provide for the evaluation of the proprietary product, and where appropriate, a comparison with current technology.

3. *Public Interest Finding (PIF)*: A PIF is an approval by the FHWA Division Administrator, based on a request from a contracting agency that it is in the public interest to allow the contracting agency to require the use of a specific material or product even though other equally acceptable materials or products are available.

To estimate the cost savings from removing the need for the above categories of approvals, FHWA estimated the number of new approvals that would be generated in the future in the above categories if the rule does not change as a baseline scenario and

compared it to a scenario with the proposed rule. The estimated number of new approvals per year is multiplied by the estimated number of hours required to process the documentation for that specific type of approval (including conducting analysis and documenting methods and results) by the appropriate labor cost (wage rate multiplied by a factor to account for employer provided benefits). Currently, the work related to approvals is conducted by both FHWA and State agencies because, in some cases, FHWA has delegated authority to States via stewardship and oversight agreements for such issues. In addition to the time required to process the approvals, time is also required by FHWA to review the resulting documentation. Finally, both of those activities require a small time allowance for management of the process.

Under the proposed rule, the costs associated with approvals for patented and proprietary materials may not be completely removed. This is because a number of States are known (according to information from FHWA Division offices) to have their own laws or policies that are similar to the FHWA requirements. Absent other information, this analysis assumes those State laws or policies would remain in place even after an FHWA rule change. For those States, this analysis assumes that the total number of hours associated with processing and managing approvals would remain unchanged but that the work would be conducted solely by State agency staff (rather than a mix of State and FHWA staff as is assumed in the baseline calculations) and that time spent on FHWA review would no longer be needed.

In addition to the cost savings that have been quantified here, there may be additional positive impacts from the rulemaking related to supporting the adoption of patented and proprietary products. Although FHWA has undertaken various efforts to grant States the flexibility to use such products, to the extent that the current rules and guidance discourage their use, the proposed rule removes those barriers. In the short term, this could lead to States paying more for proprietary and patented products if certain products are specified in Federal-aid contracts. However, ARTBA, in its petition for repeal, states that such products could “save lives, minimize congestion, and otherwise improve the quality of our nation’s highways.”<sup>13</sup> Thus, there may be

benefits associated with greater adoption of existing products. An increase in the willingness to adopt patented and proprietary products may have secondary impacts and spur additional innovation if product developers perceive there to be a larger market for new products. Those potential benefits from additional innovation have not been quantified in this analysis.

The public is invited to comment and provide information related to any aspect of this estimation of cost savings.

#### *Regulatory Flexibility Act*

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the FHWA has evaluated the effects of this action on small entities and has determined that the action is not anticipated to have a significant economic impact on a substantial number of small entities. The proposed amendment addresses obligation of Federal funds to States for Federal-aid highway projects. As such, it affects only States and States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the Regulatory Flexibility Act does not apply, and FHWA certifies that the proposed action will not have a significant economic impact on a substantial number of small entities.

#### *Unfunded Mandates Reform Act of 1995*

This proposed rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, March 22, 1995) as it will not result in the expenditure by State, local, Tribal governments, in the aggregate, or by the private sector, of \$155 million or more in any 1 year (2 U.S.C. 1532 *et seq.*). Additionally, the definition of “Federal mandate” in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

#### *Executive Order 13132 (Federalism)*

This proposed action has been analyzed in accordance with the principles and criteria contained in E.O. 13132 dated August 4, 1999, and FHWA has determined that this proposed action would not have a substantial direct effect or sufficient federalism implications on the States. The FHWA has also determined that this proposed action would not preempt any State law or regulation or affect the States’ ability

<sup>12</sup> [https://www.fhwa.dot.gov/programadmin/contracts/011106qa.cfm#\\_Hlk307505978](https://www.fhwa.dot.gov/programadmin/contracts/011106qa.cfm#_Hlk307505978).

<sup>13</sup> ARTBA, “Petition for Rulemaking to Repeal the Proprietary and Patented Products Rule 23 CFR 635.411”, March 27, 2018.

to discharge traditional State governmental functions.

*Executive Order 12372  
(Intergovernmental Review)*

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities 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. The FHWA has determined that the proposed rule does not contain collection of information requirements for the purposes of the PRA. Any action that might be contemplated in subsequent phases of this proceeding will be analyzed for the purpose of the Paperwork Reduction Act for its impact.

*National Environmental Policy Act*

The FHWA has analyzed this action for the purpose of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and has determined that this action would not have any effect on the quality of the environment and meets the criteria for the categorical exclusion at 23 CFR 771.117(c)(20).

*Executive Order 12630 (Taking of Private Property)*

The FHWA has analyzed this proposed rule under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The FHWA does not anticipate that this proposed action would affect a taking of private property or otherwise have taking implications under E.O. 12630.

*Executive Order 12988 (Civil Justice Reform)*

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

*Executive Order 13045 (Protection of Children)*

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this proposed action would not cause an environmental risk to health or safety

that might disproportionately affect children.

*Executive Order 13175 (Tribal Consultation)*

The FHWA has analyzed this action under E.O. 13175, dated November 6, 2000, and believes that the proposed action would not have substantial direct effects on one or more Indian tribes; would not impose substantial direct compliance costs on Indian Tribal governments; and would not preempt Tribal laws. The proposed rulemaking addresses obligations of Federal funds to States for Federal-aid highway projects and would not impose any direct compliance requirements on Indian Tribal governments. Therefore, a Tribal summary impact statement is not required.

*Executive Order 13211 (Energy Effects)*

We have analyzed this action under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The FHWA has determined that this is not a significant energy action under that order since it is not a significant regulatory action under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

*Regulation Identification Number*

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

**List of Subjects**

*23 CFR Part 630*

Grant programs, transportation, highways and roads.

*23 CFR Part 635*

Construction materials, Design-build, Grant programs, transportation, highways and roads.

Issued on: November 6, 2018.

**Brandye L. Hendrickson,**  
*Deputy Administrator, Federal Highway Administration.*

**Option 1**

In consideration of the foregoing, FHWA proposes to amend title 23, Code of Federal Regulations, parts 630 and 635 as follows:

**PART 630—PRECONSTRUCTION PROCEDURES**

**Subpart A—Project Authorization and Agreements**

■ 1. The authority citation for part 630 continues to read as follows:

**Authority:** 23 U.S.C. 106, 109, 112, 115, 315, 320, and 402(a); Sec. 1501 and 1503 of Pub. L. 109–59, 119 Stat. 1144; Pub. L. 105–178, 112 Stat. 193; Pub. L. 104–59, 109 Stat. 582; Pub. L. 97–424, 96 Stat. 2106; Pub. L. 90–495, 82 Stat. 828; Pub. L. 85–767, 72 Stat. 896; Pub. L. 84–627, 70 Stat. 380; 23 CFR 1.32 and 49 CFR 1.48(b), and Pub. L. 112–141, 126 Stat. 405, section 1303.

■ 2. Amend § 630.112 by adding paragraph (c)(6) as follows:

\* \* \* \* \*

(c) \* \* \*  
(6) *Competition in Products Certification*—By signing the project agreement, the State Department of Transportation (State DOT) agrees to abide by and certify that its product evaluation and selection process, and the specifications used for Federal-aid projects, will provide for fair, open, and transparent competition awarded only by contract to the lowest responsive bid submitted by a responsible bidder pursuant to 23 U.S.C. 112. By signing the project agreement, the State DOT is providing the certification required in 23 CFR 635.411(a).

\* \* \* \* \*

**PART 635—CONSTRUCTION AND MAINTENANCE**

**Subpart D—General Material Requirements**

■ 1. The authority citation for part 635 continues to read as follows:

**Authority:** Sections 1525 and 1303 of Pub. L. 112–141, Sec. 1503 of Pub. L. 109–59, 119 Stat. 1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 *et seq.*; Sec. 1041(a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.85(a)(1).

■ 2. Revise § 635.411 to read as follows:

**§ 635.411 Material or product selection.**

(a) As a condition of receiving Federal-aid funds, the State Department of Transportation (State DOT) certifies that its product evaluation process and the specifications used for Federal-aid projects will provide for fair, open, and transparent competition pursuant to 23 CFR 630.112(c)(6).

(b) State DOTs shall have the autonomy to determine culvert and storm sewer material types to be included in the construction of a project on a Federal-aid highway.

**Option 2**

In consideration of the foregoing, FHWA proposes to revise title 23, Code of Federal Regulations, part 635 as follows:

**PART 635—CONSTRUCTION AND MAINTENANCE****Subpart D—General Material Requirements**

■ 1. The authority citation for part 635 continues to read as follows:

**Authority:** Sections 1525 and 1303 of Pub. L. 112–141, Sec. 1503 of Pub. L. 109–59, 119 Stat. 1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 *et seq.*; Sec. 1041(a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.85(a)(1).

■ 2. Revise § 635.411 to read as follows:

**§ 635.411 Culvert and Storm Sewer Material Types.**

State Departments of Transportation (State DOTs) shall have the autonomy to determine culvert and storm sewer material types to be included in the construction of a project on a Federal-aid highway.

[FR Doc. 2018–24687 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–22–P

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[REG–107813–18]

RIN–1545–B082

**Hardship Distributions of Elective Contributions, Qualified Matching Contributions, Qualified Nonelective Contributions, and Earnings**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed amendments to the regulations relating to hardship distributions from section 401(k) plans. The amendments reflect statutory changes affecting section 401(k) plans, including recent changes made by the Bipartisan Budget Act of 2018. These regulations would affect participants in, beneficiaries of, employers maintaining, and administrators of plans that contain cash or deferred arrangements or provide for employee or matching contributions.

**DATES:** Comments and requests for a public hearing must be received by January 14, 2019.

**ADDRESSES:** Send submissions to CC:PA:LPD:PR (REG–107813–18) Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–107813–18), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at [www.regulations.gov/](http://www.regulations.gov/) (indicate IRS and REG–107813–18).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Roger Kuehnle at (202) 317–6060 or; concerning submissions of comments, the hearing, or to be placed on the building access list to attend the hearing, Regina L. Johnson at (202) 317–6901 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:****Paperwork Reduction Act**

The collection of information contained in this notice of proposed rulemaking will be submitted, under approval number 1545–1669, to the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by January 14, 2019. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in § 1.401(k)–1(d)(3)(iii)(B). The collection of information relates to the certification by participants in section 401(k) plans that they have insufficient cash or other liquid assets to cover expenses resulting from a hardship and, thus, will need a distribution from the plan to meet the expenses. The collections of information are required to obtain a benefit.

The likely recordkeepers are individuals.

*Estimated total annual reporting burden:* 101,250 hours.

*Estimated average annual burden per respondent:* 45 minutes.

*Estimated number of respondents:* 135,000.

*Estimated frequency of responses:* On occasion.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

**Background***Section 401(k)*

Section 401(k)(1) of the Internal Revenue Code (Code) provides that a profit-sharing, stock bonus, pre-ERISA money purchase, or rural cooperative plan will not fail to qualify under section 401(a) merely because it contains a cash or deferred arrangement (CODA) that is a qualified CODA. Under section 401(k)(2), a CODA (generally, an arrangement providing for an election by an employee between contributions to a plan or payments directly in cash) constitutes a qualified CODA only if it satisfies certain requirements. Section 401(k)(2)(B) provides that contributions made pursuant to a qualified CODA (referred to as “elective contributions”) may be distributed only on or after the occurrence of certain events, including death, disability, severance from employment, termination of the plan, attainment of age 59½, hardship, or, in the case of a qualified reservist distribution, the date a reservist is called to active duty. Section 401(k)(2)(C) requires that elective contributions be nonforfeitable at all times.

Section 401(k)(3)(A)(ii) requires that elective contributions satisfy the actual deferral percentage (ADP) test set forth in section 401(k)(3). Sections 401(k)(11), 401(k)(12), and 401(k)(13) each provide an alternative method of meeting the ADP test. Under section 401(k)(3)(D), qualified nonelective contributions (QNECs) and qualified matching contributions (QMACs), as described in