DEPARTMENT OF HEALTH AND HUMAN SERVICES

48 CFR Parts 327 and 352

RIN 0991–AB87

Health and Human Services Acquisition Regulation

AGENCY: Department of Health and Human Services; Office of the Assistant Secretary for Financial Resources and Office of Grants and Acquisition Policy and Accountability, Division of Acquisition.

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services (HHS) is proposing to amend its Federal Acquisition Regulation (FAR) Supplement—the HHS Acquisition Regulation (HHSAR)—to add two clauses, ''Patent Rights—Exceptional Circumstances'' and ''Rights in Data—Exceptional Circumstances,'' and their prescriptions.

DATES: Comments are due on or before March 11, 2013.

ADDRESSES: Submit comments in response to ''Health and Human Services Acquisition Regulation, Clauses 352.227–11 and 352.227–14'' by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering ''Health and Human Services Acquisition Regulation, Clauses 352.227–11 and 352.227–14'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''Health and Human Services Acquisition Regulation, Clauses 352.227–11 and 352.227–14.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Health and Human Services Acquisition Regulation, Clauses 352.227–11 and 352.227–14'' on your attached document.
- *Fax:* 202–690–6902.
- *Mail:* HHS/ASFR/OGAPA/Division of Acquisition, ATTN: Cheryl Howe, Room 537H, HHH Building, 200 Independence Avenue SW., Washington, DC 20201.

Instructions: Please submit comments only and cite Health and Human Services Acquisition Regulation, Clauses 352.227–11 and 352.227–14, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Cheryl Howe, Procurement Analyst, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, telephone (202) 690–5552.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this proposed rule is to ensure that providers of proprietary material(s) to the government will retain all their preexisting rights to their material(s), and rights to any inventions made under a contract or subcontract (at all tiers), when a Determination of Exceptional Circumstances (DEC) has been executed. ''Material'' means any proprietary material, method, product, composition, compound or device, whether patented or unpatented. A DEC is executed consistent with the policy and objectives of the Bayh-Dole Act, 35 U.S.C. 200, *et seq.,* to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations including universities; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against nonuse or unreasonable use of inventions; and in the case of fulfilling the mission of the U.S. Department of Health and Human Services, to ultimately to benefit the public health.

Under certain circumstances, in order to ensure that pharmaceutical companies, academia, and others will collaborate with HHS in identifying, testing, developing, and commercializing new drugs, therapeutics, diagnostics, prognostics and prophylactic measures affecting human health, a Determination of Exceptional Circumstances (DEC) must be executed, and Contractor's and subcontractor's rights (at all tiers) in subject inventions should be limited accordingly, consistent with DEC requirements and through appropriate contract clauses.

II. Proposed Rule

The proposed changes would amend the HHSAR by adding two new clauses, 352.227–11 Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances, and their respective prescriptions at 327.303 and 327.409.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, is not subject to review under section 6 of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

This change may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* The Initial Regulatory Flexibility Analysis (IRFA) is summarized as follows:

A. This action is being implemented to amend the Health and Human Services Acquisition Regulation (HHSAR) by adding two new clauses, 352.227–11 Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances, and their respective prescriptions at 327.303 and 327.409.

B. These changes are proposed to ensure that providers of proprietary materials to the government will retain their preexisting rights to their material(s), and rights to any inventions made under a contract or subcontract (at all tiers), in which the provider has a proprietary interest when a Determination of Exceptional Circumstances (DEC) has been executed.

C. This proposed rule applies to all Federal contractors and subcontractors at all tiers as applicable, regardless of size or business ownership. The resultant cost impact is considered $444,990.42. There are no known significant alternatives to the rule that would further minimize any economic impact of the rule on small entities.

D. A copy of the IRFA shown in V. below has been submitted to the Chief Counsel for Advocacy of the Small Business Administration. HHS invites comments from small entities and other interested parties on the expected impact of this rule on small entities.

E. IRFA

1. Description of the reasons why action is being taken.

This proposed rule will amend the Health and Human Services Acquisition Regulation (HHSAR) to add two new clauses, Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances. These clauses will be used in lieu of FAR clause 52.227–14 Rights in Data—General and FAR clause 52.227–11 Patent Rights—Ownership by the Contractor to address the patent and data rights of the Government, the prime contractor, the subcontractors at all tiers) and the providers of proprietary materials to the Government (providers).

2. Statement of the objectives of, and the legal basis for, the rule.

This action is being taken to ensure that providers, the majority of which are small businesses, will retain their preexisting rights to material and subject inventions in which the provider has a proprietary interest when a Determination of Exceptional Circumstances (DEC) has been executed. A DEC promotes the policy and objectives of the Bayh-Dole Act, 35 U.S.C. 200, *et seq.,* to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against nonuse or unreasonable use of inventions; and ultimately to benefit the public health. In order to ensure that pharmaceutical companies, academia, and others will collaborate with the Department of Health and Human Services (HHS) under certain conditions in identifying, testing, developing, and commercializing new drugs, therapeutics, diagnostics, prognostics and prophylactic measures affecting human health, a determination that exceptional circumstances must be executed, and Contractor's and subcontractor's rights (at all tiers) in subject inventions should be limited accordingly through appropriate contract clauses.

3. Description of and, where feasible, an estimate of the number of small entities to which the rule will apply.

The affected contracts are usually awarded using NAICS code 541711, Research and Development in Biotechnology, or NAICS code 541712 Research and Development in the Physical, Engineering, and Life Sciences (except Biotechnology). Both NAICS have a small business size standard of 500 employees. It is estimated that this rule will affect 61 prime contractors of which 4 will be small businesses (6.5%); 76 subcontractors of which 21 will be small businesses (27.6%); and 379 providers of which 189 will be small businesses (49.87%). The aforementioned figures are based on historical data from one operating division of HHS. It is anticipated that numbers will increase proportionally as the proposed clauses will be used on an HHS-wide basis. Using the proposed HHSAR clauses better addresses the requirements of the Bayh-Dole Act and provides appropriate legal protection for the proprietary rights of providers to ensure providers will collaborate with the Government and provide access to their promising proprietary material(s) to meet HHS program goals. Comments will be solicited from small businesses and other interested parties. Comments will be considered from small entities on the impact of this rule.

4. Description and estimate of compliance requirements including differences in cost, if any, for different groups of small entities.

The projected reporting, recordkeeping, or other compliance requirements projected for this rule will be carried out by the prime contractor. Only a small percentage (6.5%) of the prime contractors will be small businesses. The projected cost for compliance requirements for those small businesses will be $28,924.38.

5. Identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the rule.

The proposed rule does not duplicate, overlap, or conflict with any other Federal rules. These clauses will be used in lieu of FAR clause 52.227–14 Rights in Data—General and with FAR clause 52.227–11 Patent Rights—Ownership by the Contractor.

6. Description of any significant alternatives to the rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the rule on small entities.

In the past a significant number of FAR deviations were processed each time a DEC was executed. Using the proposed HHSAR clauses better addresses the requirements of the Bayh-Dole Act and provides solid legal protection for the proprietary rights of providers to ensure providers will collaborate with the Government and provide access to their promising proprietary material(s) to meet HHS program goals. Therefore, it is believed that the approach outlined in the proposed rule is the most practical and provides benefits to the Government, the public health and industry to ensure HHS program goals can be achieved.

F. HHS will also consider comments from small entities concerning the existing regulations in subparts affected by this rule consistent with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite HHS Acquisition Regulation in correspondence.

V. Paperwork Reduction Act

The Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35) applies because this proposed rule contains information collection requirements under the proposed clauses HHSAR 352.227–11 Patent Rights—Exceptional Circumstances, and HHSAR 352.227–14 Rights in Data—Exceptional Circumstances. This requirement has been submitted to the Office of Management and Budget for approval. Public reporting burden for this collection of information is estimated to average 11 hours per response under 352.227–11 and 6 hours under 352.227–14, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Although this requirement is new to the HHSAR, collection of this information is not new as it has been collected through use of deviated FAR clauses 52.227–11 Patent Rights—Ownership and 52.227–14 Rights in Data—General in the past.

Data from Fiscal Years 2007 through 2012 contract awards using approved FAR deviations was used to determine the burden. If this proposed reporting requirement had been in place during those Fiscal Years, it would have covered 63 cost-reimbursement contracts above the simplified acquisition threshold. For 352.227–11 Patent Rights—Exceptional Circumstances, we estimate that it will take approximately 9009 hours to prepare and submit the reports. For 352.227–14 Rights in Data—Exceptional Circumstances, we estimate that it will take approximately 2,268 hours to prepare and submit the reports. The annual reporting burden is estimated as follows for each clause:

HHSAR 352.227–11	
Respondents	63

Responses/respondent	13 × 63
Total annual Responses	819
Preparation hours per response	140 hours/13 responses = 11 hours AVG
Total response burden hours	9009
HHSAR 352.227–14	
Respondents	63
Responses/respondent	6 × 63
Total annual Responses	378
Preparation hours per response	33 hours/6 responses = 6 hours AVG
Total response burden hours	2268

Public reporting burdens indicated above for submission of the data required includes the time for gathering the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, and document identifier, to *Sherette.funncoleman@hhs.gov,* or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above email address within 60-days of this notice.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

List of Subjects in 48 CFR Parts 327 and 352

Government procurement.

For the reasons stated in the preamble, HHS proposes to amend 48 CFR parts 327 and 352 as follows:

PART 327—PATENTS, DATA, AND COPYRIGHTS

■ 1. The authority citation for 48 CFR parts 327 and 352 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

■ 2. Add subpart 327.3 to read as follows:

Subpart 327.3—Patent Rights under Government Contracts

327.303 Solicitation provision and contract clause.

The Contracting Officer shall insert the clause at 352.227–11 Patent Rights—Exceptional Circumstances and any appropriate alternates in lieu of FAR 52.227–14 whenever a Determination of Exceptional Circumstances (DEC) involving the provision of materials has been executed in accordance with Agency policy and procedures calls for its use and 352.227–11 appropriately covers the circumstances. The Contracting Officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.

■ 3. Add subpart 327.4 to read as follows:

Subpart 327.4—Rights in Data and Copyrights

327.409 Solicitation provision and contract clause.

The Contracting Officer shall insert the clause at 352.227–14 Rights in Data—Exceptional Circumstances and any appropriate alternates in lieu of FAR 52.227–14 whenever a Determination of Exceptional Circumstances (DEC) executed in accordance with Agency policy and procedures calls for its use. Prior to using this clause a Determination of Exceptional Circumstances (DEC) must be executed in accordance with Agency policy and procedures. The Contracting Officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Add section 352.227–11 to read as follows:

352.227–11 Patent rights-exceptional circumstances.

Patent Rights-Exceptional Circumstances (abbreviated month and year of Final Rule publication)

This clause applies to all Contractor and subcontractor (at all tiers) Subject Inventions.

(a) Definitions.

''Agency'' means the Agency of the U.S. Department of Health and Human Services that is entering into this contract.

''Class 1 Subject Invention'' means a Subject Invention described and defined in the DEC that will be assigned to a third party assignee, or assigned as directed by the Agency.

''Class 2 Subject Invention'' means a Subject Invention described and defined in the DEC.

''Class 3 Subject Invention'' means a Subject Invention that does not fall into Class 1 or Class 2 as defined in this clause.

''DEC'' means the Determination of Exceptional Circumstances signed by [insert approving official]____ on ____ [insert date]____ and titled ''[insert description]''

''Invention'' means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, *et. seq.*)

''Made'' means: When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of such invention; or when used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

''Material'' means any proprietary material, method, product, composition, compound or device, whether patented or unpatented, which is provided to the Contractor under this contract.

''Nonprofit organization'' means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state Nonprofit organization statute.

''Practical application'' means to manufacture, in the case of a composition or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

''Small business firm'' means a small business concern as defined at section 2 of Public Law 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3–8 and 13 CFR 121.3–12, respectively, will be used.

''Subject Invention'' means any invention of the Contractor made in the performance of work under this contract.

''Third party assignee'' means any entity or organization that may, as described in the DEC, be assigned Class 1 inventions.

(b) *Allocation of principal rights.* (1) *Retention of pre-existing rights.* Third party assignees shall retain all preexisting rights to Material in which the Third party assignee has a proprietary interest.

(2) *Allocation of Subject Invention rights.* (i) *Disposition of Class 1 Subject Inventions.* (A) *Assignment to the Third party assignee or as directed by the Agency.* The Contractor shall assign to the Third party assignee designated by the Agency the entire right, title, and interest throughout the world to each Subject Invention, or otherwise dispose of or transfer those rights as directed by the Agency, except to the extent that rights are retained by the Contractor under paragraph (b)(3) of this clause. Any such assignment or other disposition or transfer of rights will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the United States government to practice or have practiced the Subject Invention for or on behalf of the United States throughout the world. Any assignment shall additionally be subject to the ''March-in rights'' of 35 U.S.C. 203 space. If the Contractor is a U.S. nonprofit educational institution. If the Contractor is a U.S. nonprofit educational, institution it may retain a royalty free, nonexclusive, nontransferable license solely to practice the invention for noncommercial internal research.

(B) [Reserved]

(ii) *Disposition of Class 2 and 3 Subject Inventions.* Class 2 Subject Inventions shall be governed by FAR Clause 52.227–11, Patent Rights-Ownership (December 2007) (incorporated herein by reference). However, the Contractor shall grant a license in the Class 2 Subject Inventions to the Third party assignee or other party designated by the Agency as set forth in Alternate I.

(iii) Class 3 Subject Inventions shall be governed by FAR Clause 52.227–11, Patent Rights-Ownership by the Contractor (December 2007) (previously incorporated herein by reference).

(3) *Greater Rights Determinations.* The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (b)(1) of this clause in accordance with the procedures of FAR paragraph 27.304–1(c) . In addition to the considerations set forth in section 27.304–1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any Third party assignee or otherwise impede the ability of the Government or the Third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies or other approaches with potential for the diagnosis, prognosis, prevention and treatment of human diseases. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (c)(1) of this clause, or not later than eight (8) months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227–13 (incorporated herein by reference), and to any reservations and conditions deemed to be appropriate by the Agency such as the requirement to assign or exclusively license the rights to Subject Inventions to the Third party assignee. A determination by the Agency denying a request by the Contractor for greater rights in a Subject Invention may be appealed within thirty (30) days of the date the Contractor is notified of the determination to an Agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application on the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any Subject Invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) *Invention disclosure by Contractor.* The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within two months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the Agency Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was Made and all inventors. It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the Agency, the Contractor will promptly notify the Contracting Officer and DEITR of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor. If the Contractor assigns a Subject Invention to the Third party assignee, the Contractor and its employee inventors shall assist the Third party assignee in securing patent protection.

(d) *Contractor action to protect the Third party assignee's and the Government's interest.* (1) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b) of this clause; and convey title to a Third party assignee in accordance with paragraph (b) of this clause and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention Made under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the Government's rights or a Third party assignee's rights in the Subject Inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) If the Contractor is granted greater rights, the Contractor agrees to include, within the specification of any United States non-provisional patent application it files, and any patent issuing thereon, covering a Subject Invention the following statement, ''This invention was made with Government support under (identify the Contract) awarded by (identify the specific Agency). The Government has certain rights in the invention.''

(4) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all Subject Inventions or stating that there were none.

(e) *Subcontracts.* (1) The Contractor will include this clause in all subcontracts, regardless of tier, for experimental, developmental, or research work. At all tiers, the clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's Subject Inventions.

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227–13 which is incorporated by reference in paragraph (b)(2)(ii) of this clause.

(f) *Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor.* The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required by 35. U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(g) *Preference for United States industry in the event greater rights are granted to the Contractor.* Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) *March-in rights in the event greater rights are granted to the Contractor.* The Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (b)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

(i) Special provisions for contracts with Nonprofit organizations in the event greater rights are granted to the Contractor. If the Contractor is a Nonprofit organization, it shall:

(1) Not assign rights to a Subject Invention in the United States without the written approval of the Agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a Subject Invention with the inventor, including Federal employee co-inventors (but through their Agency if the Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of Subject Inventions that are small business concerns, and give a preference to a small business concern when licensing a Subject Invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to Practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) *Communications.* All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as directed by the Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to:

[INSERT Agency ADDRESS]

Agency Invention Reporting Web site: *http://www.iEdison.gov*

Alternate I

As prescribed in 327.303, the license to Class 2 inventions recited in 352.227–11(b)(2)(a) is as follows:

[insert description of license to Class 2 inventions]

(End of clause)

352.227–14 Rights in data—exceptional circumstances.

As prescribed in 327.409(b)(1), insert the following clause with any appropriate alternates:

Rights in Data—Exceptional Circumstances (abbreviated month and year of Final Rule publication)

(a) *Definitions.* As used in this clause—

[Definitions may be added or modified in paragraph (a) as applicable.]

''Computer database'' or ''database means'' a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

''Computer software''—

(i) Means

(A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

(B) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

(ii) Does not include computer databases or computer software documentation.

''Computer software documentation'' means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

''Data'' means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

''Form, fit, and function data'' means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

''Limited rights'' means the rights of the Government in limited rights data as set forth

in the Limited Rights Notice in Alternate II paragraph (g)(3) if included in this clause.

''Limited rights data'' means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

''Restricted computer software'' means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

''Restricted rights,'' as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of Alternate III paragraph (g)(4) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

''Technical data'' means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).

''Unlimited rights'' means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) *Allocation of rights.* (1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in—

(i) Data first produced in the performance of this contract;

(ii) Form, fit, and function data delivered under this contract;

(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and

(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to—

(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;

(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) *Copyright.* (1) *Data first produced in the performance of this contract.* (i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of *17 U.S.C. 401 or 402,* and an acknowledgment of Government sponsorship (including contract number).

(iii) For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.

(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor—

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) Removal of copyright notices. The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except—

(1) As prohibited by Federal law or regulation (*e.g.,* export control or national security laws or regulations);

(2) As expressly set forth in this contract; or

(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer or in the following paragraphs.

(4) In addition to any other provisions set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any proposed publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 352.227–11, Patent Rights—Exceptional Circumstances (abbreviated month and year of Final Rule publication).

(5) Data on Material(s). The Contractor agrees that in accordance with paragraph (d)(2), proprietary data on Material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) Confidentiality. (i) The Contractor shall take all reasonable precautions to maintain Confidential Information as confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes/does not include: [Government may define confidential information here.]

(e) *Unauthorized marking of data.* (1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (4) of this clause (if those alternate paragraphs are included in this clause), and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may cancel or ignore the markings. However, pursuant to *41 U.S.C. 253d,* the following procedures shall apply prior to canceling or ignoring the markings.

(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting

Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final Agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph (e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with Agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request there under.

(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph (e) from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

(f) *Omitted or incorrect markings.* (1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor—

(i) Identifies the data to which the omitted notice is to be applied;

(ii) Demonstrates that the omission of the notice was inadvertent;

(iii) Establishes that the proposed notice is authorized; and

(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may—

(i) Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) *Protection of limited rights data and restricted computer software.* (1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs (b)(1)(i) through (iii) of this clause. As a condition to this withholding, the Contractor shall—

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) *Subcontracting.* The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) Relationship to patents or other rights. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause)

Alternate I (abbreviated month and year of Final Rule publication). As prescribed in 327.409, substitute the following definition for ''limited rights data'' in paragraph (a) of the basic clause:

''Limited rights data'' means data, other than computer software, developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged.

Alternate II (abbreviated month and year of Final Rule publication). As prescribed in 327.409, insert the following paragraph (g)(3) in the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following ''Limited Rights Notice'' to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (abbreviated month and year of Final Rule publication)

(a) These data are submitted with limited rights under Government Contract No. _____ (and subcontract _____, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: [*Agencies may list additional purposes or if none, so state.*]

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

Alternate III (abbreviated month and year of Final Rule publication). As prescribed in 327.409, insert the following paragraph (g)(4) in the basic clause:

(g)(4)(i) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of restricted computer software, or the Contracting Officer may require by written request the delivery of restricted computer software that has been withheld or would otherwise be entitled to be withheld. If delivery of that computer software is required, the Contractor shall affix the following ''Restricted Rights Notice'' to the computer software and the Government will treat the computer software, subject to paragraphs (e) and (f) of this clause, in accordance with the notice:

Restricted Rights Notice (abbreviated month and year of Final Rule publication)

(a) This computer software is submitted with restricted rights under Government Contract No. _____ (and subcontract _____, if appropriate). It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract.

(b) This computer software may be—

(1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred;

(2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, *provided* that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights;

(5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and

(6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice.

(d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract.

(e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice)

(ii) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form notice may be used instead:

Restricted Rights Notice Short Form (abbreviated month and year of Final Rule publication)

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. _____ (and subcontract, if appropriate) with _____ (name of Contractor and subcontractor).

(End of notice)

(iii) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401, it will be presumed to be licensed to the Government without disclosure prohibitions, with the minimum rights set forth in paragraph (b) of this clause.

Alternate IV (abbreviated month and year of Final Rule publication). As prescribed in 327.409, substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c) *Copyright*—(1) *Data first produced in the performance of the contract.* Except as otherwise specifically provided in this contract, the Contractor may assert copyright in any data first produced in the performance of this contract. When asserting copyright, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number), to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public), by or on behalf of the Government.

Alternate V (abbreviated month and year of Final Rule publication). As prescribed in 327.409, add the following paragraph (j) to the basic clause:

(j) The Contractor agrees, except as may be otherwise specified in this contract for specific data deliverables listed as not subject to this paragraph, that the Contracting Officer may, up to three years after acceptance of all deliverables under this contract, inspect at the Contractor's facility any data withheld pursuant to paragraph (g)(1) of this clause, for purposes of verifying the Contractor's assertion of limited rights or restricted rights status of the data or for evaluating work performance. When the Contractor whose data are to be inspected demonstrates to the Contracting Officer that there would be a possible conflict of interest if a particular representative made the inspection, the Contracting Officer shall designate an alternate inspector.

Dated: September 18, 2012.

Angela Billups,

Associate Deputy Assistant Secretary for Acquisition.

[FR Doc. 2012–31490 Filed 1–9–13; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. NHTSA–2010–0132]

RIN 2127–AK17

Federal Motor Vehicle Safety Standards; New Pneumatic Tires for Motor Vehicles With a GVWR of More Than 4,536 Kilograms (10,000 Pounds) and Motorcycles

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: This document proposes several minor amendments to Federal Motor Vehicle Safety Standard (FMVSS) No. 119 to revise the formatting and replace a missing footnote in Table II. FMVSS No. 119 was amended in a final rule published on June 26, 2003 as part of a comprehensive upgrade of several FMVSSs to improve tire safety, as required by the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act of 2000. The agency believes that this proposed revision is appropriate to correct minor oversights made in the June 2003 final rule for FMVSS No. 119.

DATES: Submit comments on or before March 11, 2013.

ADDRESSES: You may submit comments electronically to the docket identified in the heading of this document by visiting the following Web site:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

Alternatively, you can file comments using the following methods:

• *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

• *Fax:* (202) 493–2251.

Regardless of how you submit your comments, you should mention the docket number identified in the heading of this document.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the Supplementary Information section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Abigail Morgan, Office of Crash Avoidance Standards (Telephone: 202–366–6005; Fax: 202–493–2990). For legal issues, you may contact David Jasinski, Office of the Chief Counsel (Telephone: 202–366–2992; Fax: 202–366–3820). You may send mail to both of these officials at the National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Background

Federal Motor Vehicle Safety Standard (FMVSS) No. 119, New pneumatic tires for motor vehicles with a gross vehicle weight rating (GVWR) of more than 4,536 kilograms (10,000 pounds) and motorcycles, specifies tire