instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

List of Subjects in 33 CFR Part 110

Anchorage grounds.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 110 as follows:

PART 11—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 110.157, revise paragraph (a)(11) to read as follows:

§ 110.157 Delaware Bay and River.

(a) * * *

(11) *Anchorage 10 at Naval Base, Philadelphia.* On the north side of the channel along West Horseshoe Range, bounded as follows: Beginning off of the southeasterly corner of Pier 1 at 39°53′07″ N., 075°10′30″ W., thence south to the to the north edge of the channel along West Horseshoe Range to 39°52′58″ N., 075°10′29″ W., thence east along the edge of the channel to 39°52′56″ N., 075°09′53″ W., thence north to 39°53′07″ N., 075°09′54″ W., thence continuing west to the beginning point at 39°53′07″ N., 075°10′30″ W.

* * * * *

Dated: December 17, 2015.

Stephen P. Metruck,

Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 2015–33167 Filed 1–4–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP35

Copayments for Medications Beginning January 1, 2017

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations concerning copayments charged to certain veterans for medication required on an outpatient basis to treat non-service connected conditions. VA currently charges non-exempt veterans either $8 or $9 for each 30-day or less supply of medication, and under current regulations, a calculation based on the prescription drug component of the Medical Consumer Price Index would be used to determine the copayment amount in future years. This rulemaking would eliminate the formula used to calculate future rate increases and establish three classes of medications, identified as Tier 1, Tier 2, and Tier 3. These tiers would be defined further in the rulemaking and would be distinguished in part based on whether the medications are available from multiple sources or a single source, with some exceptions. Copayment amounts would be fixed and would vary depending upon the class of medication. The following copayment amounts would be effective January 1, 2017: $5 for a 30-day or less supply of a Tier 1 medication, $8 for a 30-day or less supply of a Tier 2 medication, and $11 for a 30-day or less supply of a Tier 3 medication. For most veterans these copayment amounts would result in lower out-of-pocket costs, thereby encouraging greater adherence to prescribed medications and reducing the risk of fragmented care that results when veterans use multiple pharmacies to fill their prescriptions.

DATES: *Comment Date:* Comments must be received by VA on or before March 7, 2016.

ADDRESSES: Written comments may be submitted by email through *http://www.regulations.gov;* by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP35–Copayments for Medications Beginning January 1, 2017.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kristin Cunningham, Chief Business Office (10NB), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 382–2508. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1722A(a), VA must require veterans to pay a $2 copayment for each 30-day supply of medication furnished on an outpatient basis for the treatment of a non-service-connected disability or condition, unless the veteran is exempt from having to pay a copayment because the veteran has a service-connected disability rated 50 percent or more, is a former prisoner of war, or has an annual income at or below the maximum annual rate of VA pension that would be payable if the veteran were eligible for pension. Under 38 U.S.C. 1722A(b), VA ''may,'' by regulation, increase that copayment amount and establish a maximum annual copayment amount (a ''cap''). We have consistently interpreted section 1722A(b) to mean that VA has discretion to determine the appropriate copayment amount (as long as that amount is at least $2) for medication furnished on an outpatient basis for covered treatment, provided that any increase in the copayment amount or annual cap is the subject of a rulemaking proceeding. VA is also prohibited under 38 U.S.C. 1722A(a)(2) from requiring a veteran to pay an amount in excess of the cost to VA. We have implemented this statute in 38 CFR 17.110.

Under 38 CFR 17.110(b)(1), veterans are obligated to pay a copayment for each 30-day or less supply of medication provided by VA on an outpatient basis (other than medication administered during treatment). Under the current regulation, for the period from July 1, 2010, through December 31, 2015, the copayment amount for veterans in priority categories 2 through 6 of VA's health care system is $8. 38 CFR 17.110(b)(1)(i). For the period July 1, 2010, through December 31, 2015, the copayment amount for veterans in priority categories 7 and 8 is $9. 38 CFR 17.110(b)(1)(ii). Thereafter, the

copayment amount for all affected veterans is to be established using a formula based on the prescription drug component of the Medical Consumer Price Index (CPI–P), set forth in regulation in 38 CFR 17.110(b)(1)(iii).

Current § 17.110(b)(2) also includes a ''cap'' on the total amount of copayments in a calendar year for a veteran enrolled in one of VA's health care enrollment system priority categories 2 through 6. Through December 31, 2015, the annual cap is set at $960. Thereafter, the cap increases ''by $120 for each $1 increase in the copayment amount'' applicable to veterans enrolled in one of VA's health care enrollment system priority categories 2 through 6.

VA has found that the current regulatory model has produced and will continue to produce copayment amounts that increase at a higher rate than the larger, non-VA retail market for prescribed medications. For this reason, VA has published a series of rulemakings that have ''frozen'' copayments from 2009 to the present. In these rulemakings, we stated that these freezes were appropriate because higher copayments reduce the utilization of VA pharmacy benefits. Even with the freezes VA has instituted, however, VA's copayment rates have exceeded those charged in other pharmacy benefits programs.

In addition to higher copayments increasing the risk that veterans will not fill their prescriptions, VA's lack of competitive copayment pricing increases the likelihood that veterans will obtain their prescribed medications from other sources. Fragmentation of prescription records to more than one pharmacy increases the risk of an incomplete medication record, which can lead to unintended adverse reactions. Different clinicians caring for the patient may not be aware of all the medications that the patient is taking. VA medical providers need to be aware of all of the medications a veteran is taking to avoid unintended prescribing of contraindicated medications. Through this rulemaking, we believe that we can prevent or minimize these unintended or adverse effects of patients choosing multiple pharmacies to fill their prescriptions.

A large body of academic research supports this position. Researchers have found that prescription copayments can affect medication adherence (Lieberman, D.A., J.M. Polinski, N.K. Choudhry, J. Avorn, and M.A. Fischer. 2014. Unintended consequences of a Medicaid prescription copayment plan. Medical Care. 52(5):422). Research also has found that higher copayment levels are associated with poor adherence, discontinuation, and non-initiation of therapy (Mann, B.S., L. Barnieh, K. Tang, D.J.T. Campbell, F. Clement, B. Hemmelgarn, M. Tonelli, D. Lorenzetti, B.J. Manns. Association between drug insurance cost sharing strategies and outcomes in patients with chronic diseases: a systematic review. PLOS ONE. 9(3):e89168). These findings are evident in a veteran study regarding lipid-lowering medication adherence. (Doshi, J.A., Zhu, J., Lee, B.Y., Kimmel, S.E., Volpp, K.G. 2009. Impact of a Prescription Copayment Increase on Lipid-Lowering Medications Adherence in Veterans. Circulation. 2009;119:390–397.). Other studies have also found that high copayment requirements can negatively influence adherence to prescription medication plans (Kazerooni, R., K. Vu, A. Tazikawa, C. Broadhead, and A.P. Morreale. Association of copayment and socioeconomic status with hormonal contraceptive adherence in a female veteran population. 2014. Women's Health Issues. 24(2):e237). Another team of researchers found that adherence rates are negatively affected by copayment rates, and that these effects vary based upon the disease burden of the patient; they also found that patients with low-comorbidity risks were more likely to be more affected by copayments, which may subsequently lead to adverse events that require more intensive and expensive health care services (Wang, V., C.F. Liu, C.L. Bryson, N.D. Sharp, and M.L. Maciejewski. 2011. Does medication adherence following a copayment increase differ by disease burden? HSR: Health Services Research. 46(6):1963).

The proposed rule would focus on the type of medication being prescribed and would remove the automatic escalator provision, meaning that changes in copayments would only occur through subsequent rulemakings. Veterans exempt by law from copayments under 38 U.S.C. 1722A(a)(3) would continue to be exempt. VA proposes to include a definition of ''medication'' and to establish three classes of medications: Tier 1 medications, Tier 2 medications, and Tier 3 medications. Tiers 1 and 2 would include multi-source medications, a term that would be defined in § 17.110(b)(1)(iv). Tier 3 would include medications that retain patent protection and exclusivity and are not multi-source medications. Copayment amounts would vary depending upon the Tier in which the medication is classified. A 30-day or less supply of Tier 1 medications would have a copayment of $5. For Tier 2 medications, the copayment would be $8, and for Tier 3 medications, the copayment would be $11.

This proposed change would provide a financial benefit to many veterans because it would reduce their copayment liabilities for most medications and their overall liability under the copayment cap. An average veteran would be better off under this model than the current approach in nearly every scenario; the sole exception is veterans who only fill Tier 3 medications, but even this group would face the same copayment liabilities under the current regulation in 2017, and would face higher copayments in future years. These veterans would also often pay substantially more in the private sector to fill the same prescriptions. Based on a comparison of the current and proposed copayment amounts, we anticipate that most veterans would realize between a 10 and 50 percent reduction in their overall pharmacy copayment liability each year based on historic utilization patterns. By our estimates, 94 percent of copayment eligible veterans would experience no cost increase, and 80 percent would realize a savings of between $1 and $5 per 30-day equivalent of medications. The proposed copayment amounts intends to support patient adherence, reduce instances of veterans not filling prescription medications and assisting veteran health improvements from chronic disease. The following table shows how copayments would vary for veterans and different types of medications. Annual savings would be even greater for veterans with a large number of medication copayments. VA estimates that at least 50 percent of all billable prescriptions would be in Tier 1, with no more than 35 percent in Tier 2, and approximately 15 percent in Tier 3. Exact estimates for Tier 1 and Tier 2 are not possible at this time and would depend on the final list of medications selected for Tier 1.

TABLE 1—TYPICAL USER, ANNUAL COST OF COPAYMENTS, CALENDAR YEAR 2017

Medication distribution	Tiered copayment proposal	Current regulation	Potential annual savings under tiered proposal
100% Tier 1	$150	$330	$180
50% Tier 1, 50% Tier 2	195	330	135
100% Tier 2	240	330	90
50% Tier 1, 50% Tier 3	240	330	90
100% Tier 3	330	330	0

Initially, VA would make a clarifying amendment to § 17.110(a) to define the term ''medication.'' As noted previously, VA is required by 38 U.S.C. 1722A to charge veterans at least a $2 copayment for each 30-day or less supply of medication furnished on an outpatient basis for the treatment of non-service-connected disabilities or conditions, unless the veteran is otherwise exempt. VA has interpreted the term ''medication'' in the past to include prescription and over-the-counter medications as determined by the Food and Drug Administration (FDA), but not medical supplies and nutritional items. This change would clarify that interpretation in regulation. Medical supplies and nutritional items, such as bandages, diabetic supplies, and catheters, would be excluded from the definition of medication, and hence not subject to the medication copayment requirements of this section. These are not considered medications and are not regulated by FDA as such, and consequently should be excluded from this definition.

Medications are conventionally classified as either ''generic'' or ''brand name'' medications, and generic medications generally are less expensive and more available than brand name medications. However, this simple classification does not capture all of the factors that affect the price and availability of medications. For example, when a brand manufacturer's patent protection and/or regulatory exclusivity ends, it sometimes authorizes the marketing of its brand name medication under a private label at generic prices; the FDA describes these products as ''authorized generics'' at 21 CFR 314.3. In addition, even without the entry of an authorized generic, the price of most brand name drugs declines as generic competitors enter the market. Because generic medications, authorized generic medications, and brand name medications that face competition from generic medications typically are sold at lower prices than brand name medications that do not face such competition, VA would include all three classes of medications in a single class for copayment purposes. Because brand name medications that face competition from generic medications may still be sold at a higher price than their generic equivalents, however, VA would only include those brand name medications that face generic competition and are procured by VA under a contracting strategy in place that makes the brand name medication lower in cost than other generic sources. VA would be able to determine if these medications are lower in cost because the contracting strategy would have reviewed available prices and identified prices that are preferable to generic competition.

Some medications also have multiple brand name products capable of being substituted because they work in the same way and in a comparable amount of time with the same active ingredients. This competition between brand name medications generally results in a lower price and so, VA would also include them in the same class as generic medications, authorized generic medications, and brand name medications that face competition from generic medications and are procured by VA under a contracting strategy in place that makes the brand name medication lower in cost than other generic sources. To avoid confusion that could arise by placing brand name medications and generic medications in the same class, VA would simply refer to these four types of medications together as multi-source medications. The term multi-source medication would be defined in § 17.110(b)(1)(iv)(A). VA would then designate medications as Tier 1, Tier 2, and Tier 3. The first two tiers would consist of multi-source medications, but those in Tier 1 would have been selected by VA using a process described below and would be available at a lower copayment than medications in Tier 2. Tier 3 medications would include all other medications and would have the highest copayment amount.

VA proposes to amend § 17.110(b)(1) by revising the subparagraphs that currently identify the copayment rates for different priority groups of veterans. Specifically, VA would revise paragraph (b)(1)(i) to state that the copayment amount for a 30-day or less supply of Tier 1 medications, as defined in paragraph (b)(1)(iv), is $5. Paragraph (b)(1)(ii) of this section would state the copayment amount for a 30-day or less supply of Tier 2 medications is $8, and paragraph (b)(1)(iii) of this section would state the copayment amount for a 30-day or less supply of Tier 3 medications is $11.

These copayment amounts are cost competitive with other health care plans, while still in line with VA's appropriated resources. Many large retailers offer a limited range of generic or multi-source medications between $1 and $4, but these plans often include premiums of more than $10 per month. VA does not charge veterans a premium, so their only out-of-pocket costs are the copayment amounts. In this context, we believe the $5 and $8 copayment amounts are comparable to what many veterans would pay for selected generic or multi-source medications from these retailers. The $11 amount for Tier 3 medications is a small increase ($2) for veterans in priority groups 7 and 8, and a modest increase ($3) for veterans in priority groups 2 through 6. The vast majority of our billable prescriptions (85 percent) are for medications that would be categorized as Tier 1 or Tier 2. For veterans receiving Tier 1 medications, there would be a price decrease of $3 in priority groups 2 through 6 and $4 in priority groups 7 and 8. The price for Tier 2 medications would remain unchanged for veterans in priority groups 2 through 6, but veterans in priority groups 7 and 8 would experience a ($1) price decrease for medications in this category. Even with an increase in the copayment amount for Tier 3 medications from their current levels, VA's pharmacy copayments for these drugs would remain a significant

value for veterans, as many non-VA pharmacy plans charge $20, $30, or $40 or more for brand name medications, which comprise the bulk of Tier 3 medications, in addition to regular premiums. Moreover, the pharmacy copayment amounts calculated using the existing regulations currently exceed $11 for veterans in priority categories 2 through 8.

VA estimates that the copayment amounts would increase three times over 6 years if the current regulations are left unchanged. These increases are projected using the current regulation's methodology because VA has taken action to freeze medication copayments over the last several years, which has generated greater separation from the initial CPI–P as of September 30, 2001.

VA would define the three classes of medications in proposed paragraph (b)(1)(iv)(B)–(D), which would be Tier 1, Tier 2, and Tier 3 medications.

As briefly described above, VA would define a ''multi-source medication'' that could be included in either Tier 1 or Tier 2 to include four types of medications. First, this would include a medication that has been and remains approved by the FDA either under sections 505(b)(2) or 505(j) of the Food, Drug, and Cosmetic Act (FDCA, 21 U.S.C. 355) and that has an A-rating in the current version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), or under section 351(k) of the Public Health Service Act (PHSA, 42 U.S.C. 262) and that has been granted an I or B rating in the current version of FDA's Lists of Licensed Biological Products with (1) Reference Product Exclusivity and (2) Biosimilarity or Interchangeability Evaluations (the Purple Book). Second, a multi-source medication would also include medications that have been and remain approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a) and which are referenced by at least one FDA-approved product that meets the first definition of multi-source medication. These medications would be included only if they are covered by a contracting strategy in place with pricing such that it is lower in cost than other generic sources. Third, multi-source medications would include those medications that have been and remain approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a) and have the same active ingredient(s), work in the same way and in a comparable amount of time, and are determined by VA to be substitutable for another medication that has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a). Insulin and levothyroxine are two examples of such medications. Finally, multi-source medications would also include a listed drug, as defined in 21 CFR 314.3, that has been approved under FDCA section 505(c) and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug. These definitions cover the full range of medications that are broadly available and lack patent protection and exclusivity and which can be procured at a low price. This includes all generic medications, as well as brand name medications that are marketed as generic medications and medications with multiple substitutable options. Such medications are widely prescribed and used by both VA and non-VA providers and represent generally the lowest cost medications available. As such, these are ideally suited for a lower copayment rate.

VA offers these medications to address a variety of chronic conditions common in our patient population, such as diabetes mellitus, hypertension, and hypercholesterolemia. If a significant portion of these prescriptions are filled with VA because of this rule, the potential clinical benefits could be far-reaching and significant, and therefore, we would encourage the use of these drugs by providing lower copayments. (We also note that, in addition to being a clear benefit to our veteran patients, far-reaching improved health outcomes would necessarily lead to lower future health care costs, although we cannot quantify these predicted cost benefits.) VA would separate multi-source medications into two categories: Tier 1 medications and Tier 2 medications. Tier 1 medications would be multi-source medications that meet all of the criteria in proposed paragraph (b)(2) as explained in further detail below. Tier 2 would include multi-source medications that do not meet all of the criteria in (b)(2).

Tier 3 medications would be defined as a medication approved by the FDA under a New Drug Application (NDA) or a biological product approved by the FDA pursuant to a biologics license agreement (BLA) that retains its patent protection and exclusivity and is not a multi-source medication identified in paragraph (b)(1)(iv)(A)(3). FDA publishes a list of the medications that have been approved under NDAs on its Web site at *www.fda.gov.*

Proposed paragraph (b)(2) would identify how VA will determine whether a multi-source medication qualifies as a Tier 1 medication; all other multi-source medications would be Tier 2 medications under proposed paragraph (b)(1)(iv)(C). Although we believe that lowering copayments for prescription medications would improve clinical outcomes for veterans who take those medications, for budgetary reasons we must limit the number of medications that would qualify for a lower copayment amount as selected multi-source medications. This limitation should effectively target VA's health care resources to achieve maximum health benefits for veterans. For example, the reduction in copayments for affected medication must be significant enough to increase the likelihood that veterans would choose to fill their medications with VA, thereby leading to the clinical benefits we discuss above. Reducing the copayment amount for a limited group of medications that are used on a long-term basis by a large number of veterans would allow us to reduce the copayment by a significant amount while still extending this financial and clinical benefit to as many veterans as possible.

Accordingly, in addition to excluding Tier 3 medications through the definition of the term ''multi-source medication,'' VA proposes to use seven exclusionary criteria to limit the medications that would be considered as Tier 1 medications entitled to the lowest copayment amount of $5. A medication must meet all of these criteria to be selected as a Tier 1 medication. These criteria would appear in proposed paragraph (b)(2) and its subparagraphs. VA would use these criteria not less than once per year to select which medications would qualify as Tier 1 medications. This annual (or more frequent) review would ensure that VA regularly reviews new medications and changes in prescription patterns and patient needs.

The first five criteria appear in paragraph (b)(2)(i). The first, in proposed paragraph (b)(2)(i)(A), would be that VA's acquisition cost for the medication must be less than or equal to $10 for a 30-day supply of medication. This is an economic criterion designed to limit the effects of the proposed rule on VA's overall budget. The $10 amount is currently the greatest amount that VA may consider while also keeping the cost of the reduced copayment amounts within acceptable budgetary limits.

Second, in proposed paragraph (b)(2)(i)(B), VA would exclude topical

creams, products used to treat musculoskeletal conditions, antihistamines, and steroid-containing medications. These classes of medications generally are used on an ''as needed'' basis, and the quantity dispensed is not uniform for topical creams, lotions, and ointments. These medications would be excluded because they are not often used to treat chronic conditions, and their inclusion would result in a loss of revenue beyond what VA can support within its appropriated resources. Finally, excluding medications that are often used for short time periods and/or for acute skin infections or conditions is consistent with the criterion in proposed paragraph (b)(2)(i)(E), below.

Third, under proposed paragraph (b)(2)(i)(C), we would require that the medication be on the VA National Formulary (VANF). The VANF is a list of medications approved by VA for VA patients based on considerations of safety, quality, effectiveness, and the ability of the medications to meet the needs of VA's unique patient population. Requiring a medication to be on the VANF ensures that VA has already reviewed the medication in terms of its safety, quality, effectiveness, and general applicability, thereby ensuring sound clinical care. Medications that are not on the VANF are not approved on a national level, even if they may have specialized uses and may be appropriate for prescribing in individual cases. Non-formulary medications can be prescribed by VA when clinically warranted, on a case-by-case basis. However, these medications are much less likely to meet VA's goal of reaching the largest number of VA patients possible through this rulemaking. In addition, a drug may not be included on the VANF because we have determined that another medication from the same drug class is selected based on clinical effectiveness. Finally, many non-VANF drugs are prescribed by VA clinicians to treat conditions with a low prevalence among veterans or to treat non-chronic conditions. Requiring that the medication be on the VANF is medically appropriate and consistent with the purposes of this rulemaking. VA periodically revises the medications that appear on the formulary, and to the extent it appears that a drug meets the other criteria of this proposed rule, and a lower copayment for that drug would serve the clinical objectives animating this rulemaking, we would consider adding the drug to the VANF.

Fourth, under proposed paragraph (b)(2)(i)(D), VA would exclude antibiotics that primarily are used for short periods of time to treat infections. These medications may lead to harmful health outcomes if overprescribed, and this exclusion is intended to support clinical care. A veteran in need of antibiotics for a short-term illness likely only pays a single copayment for this prescription during the course of a year. Accordingly, the clinical incentive for patient medication adherence over time that VA intends to promote through this rulemaking is less relevant for these medications.

Fifth, under proposed paragraph (b)(2)(i)(E), VA would only consider medications that primarily are prescribed to either treat or manage a chronic condition, or to reduce the risk of adverse health outcomes of secondary conditions that are often more dangerous than the chronic condition itself. We believe this is crucial to maximizing the clinical benefit under this proposed rule. For example, VA would select medications used to treat high blood pressure because they reduce the risks of heart attack, stroke, and kidney failure. Some examples of chronic conditions prevalent among veterans include hypertension (more than 40 percent of enrolled veterans), diabetes (25 percent), and various types of heart disease (between 5 and 10 percent). VA anticipates that reducing copayments for medications treating these conditions would improve health outcomes for veterans by increasing the rate of adherence to prescribed medication regimens. VA may also benefit from secondary cost savings resulting from improved health outcomes and reduced demand for high cost treatments, such as surgery, for potentially life-threatening conditions that could have been prevented.

This criterion is also crucial because it serves to focus budgetary resources onto drugs used to treat and prevent conditions for which we expect the clinical benefits of this proposed rule will be the most pronounced. Improving our ability to monitor patients' compliance and increased patient compliance with treatment plans would have the most dramatic health benefits for veterans who take medications that fall within this criterion. It is well established that adherence to medications used in the management of chronic diseases such as hypertension, diabetes, hyperlipidemia and heart disease slows progression of major diseases that result in disability and increased consumption of health care resources.

Further, we propose that conditions that persist for 3 months or more will be considered chronic. We are aware that 38 CFR 3.317(a)(4) provides that a condition must persist for 6 months before it may be considered chronic. However, that section is designed to identify conditions that form the basis of a monthly monetary payment of compensation, which is a different goal than the treatment of a medical condition. Treating a persistent medical condition can be critical in preventing additional or worsening symptoms as well as secondary illnesses. Moreover, § 3.317(a)(4) of 38 CFR deals with undiagnosed illnesses arising out of the comparatively narrow context of the Gulf War. When a disease is difficult to diagnose, requiring a longer period of persistence helps VA ensure that condition in question actually is chronic as that term is commonly understood. We would also apply this criterion to conditions, not to individual patients. For example, just because it is technically possible for a common cold to persist for 3 months does not mean that colds are chronic. Rather, conditions which typically persist for 3 months in most or all patients would meet this criterion. For example, VA would select medications used to treat high blood pressure because that condition typically persists for more than 3 months and, under the proposed rule, we would charge the $5 copayment for such medication (as long as it met all other criteria) regardless of whether the patient for whom the medication is prescribed has actually been diagnosed as having had high blood pressure for 3 months.

Under the sixth criterion in proposed paragraph (b)(2)(ii), we would consider, among those medications that satisfy all of the criteria in paragraph (b)(2)(i), those medications that are among the top 75 most commonly prescribed multi-source medications based on the number of prescriptions issued for a 30-day or less supply on an outpatient basis during a fixed period of time to determine our annual list of Tier 1 medications. This would enable VA to consider veteran utilization when adopting the list. By looking at how many prescriptions are filled by veterans, VA can identify those medications that are in greatest demand and reduce their copayments, thereby providing the greatest benefit to veterans in terms of cost reduction. VA clinicians are also most likely to prescribe medications that have the greatest clinical benefit to veterans, and as a result, veterans are also likely to benefit from improved health care delivery. This factor would also ensure that, as the clinical needs of veterans change, VA reassesses the list to determine if new drugs should qualify

or if drugs currently identified as selected should be removed. VA proposes to identify up to 75 medications under this paragraph because this number would allow VA to identify a broad spectrum of pharmaceuticals while limiting the potential budgetary impact of reduced copayment collections. VA would review utilization data for a fixed period of time, likely a 12-month period either consisting of a fiscal year or a calendar year. This requirement would allow VA to regularly assess the available data and make any necessary changes.

After identifying the top multi-source medications prescribed that also satisfy the criteria in paragraph (b)(2)(i), VA would evaluate these medications to determine their clinical value under the seventh criterion, which appears in proposed paragraph (b)(2)(iii), and in the context of VA's available budgetary resources, as described in more detail below. VA would make a medical determination concerning the clinical value of each entry on the list of the most utilized medications. New developments, such as a shift in the health care needs of the veteran population, newly released data or clinical treatment guidelines, or newly released multi-source medications could help VA determine which medications should be Tier 1 medications, but the possible range of factors are too numerous to be set forth in regulation. For example, many veterans have cardiovascular conditions that require treatment or management, such as high blood pressure, high cholesterol, heart disease, diabetes, and others. VA would take the prevalence of these conditions into account when selecting medications to ensure that a large number of veterans would be able to receive medications at a reduced copayment. As another example, VA would consider the recommendations of clinical practice guidelines it follows in the treatment of serious, chronic conditions. These clinical practice guidelines are developed in consultation with experts in each disease and are based on the latest available research in terms of efficacy and health outcomes. A medication that is identified as a first course of treatment would likely receive preference over a medication that is primarily used as second treatment option. In a similar way, VA would also look to empirical data on morbidity and mortality rates for conditions following treatment with certain medications. If one medication does a better job at improving health outcomes than another based on these measures, VA would likely select that better performing medication. There may be certain medications that treat a larger segment of the population than others, and VA would likely consider these attributes as well. If one medication is particularly effective with a sub-group, but is less effective with the average patient, it would be less likely to be selected. Similarly, VA may apply public health principles to identify conditions that are either under-treated or that, if treated early, can prevent the onset of more complex conditions that are more expensive to treat. For example, VA may look for medications that treat glaucoma or osteoporosis, which have a low prevalence in the veteran population, but that if treated and managed early can prevent more serious conditions such as blindness or broken bones. Ultimately, these determinations would be made by VA using the clinical expertise of its physicians, pharmacists, public health specialists, and other clinicians as appropriate to ensure that VA is able to offer at a reduced copayment the right mix of medications for its patient population. This approach is commonly used by other health care plans to select medications under their pharmacy benefits programs. As new multi-source medications become approved and available, VA would need to reassess this list and, as the health profile of its patient population changes, VA would need to maintain flexibility to ensure that the medications identified for a reduced copayment are appropriate.

The purpose of the criterion of clinical value in paragraph (b)(2)(iii) would be to ensure that those medications that would most improve clinical care would be available at a reduced copayment; however, we note that this evaluation should not be read to suggest that other multi-source mediations do not have clinical value. The Tier 1 and Tier 2 classifications are designed simply to distinguish between two similar classes of medications and do not reflect on the quality of the medication itself. VA would make determinations regarding which medications should be included in Tier 1 in light of available budgetary resources to ensure that it does not select more medications than it can afford to maintain at a reduced copayment amount.

The decision regarding which medications qualify for Tier 1 would also be made in the context of VA's available budgetary resources, as noted in proposed paragraph (b)(2)(iii). Each year, VA assembles a budget request that is carefully calculated based on its enrolled patient population, their clinical needs, and the cost of delivering health care. Included in VA's budget projections is an estimate for how much VA will receive from first- and third-party payers for certain types of treatment. These payments are deposited into the Medical Care Collections Fund (MCCF). Medication copayments are one source of revenue for the MCCF. In each year's budget recommendation submitted by VA, we identify the MCCF estimates, and in each budget enacted by Congress, the MCCF estimates are also included. VA's budget for the Medical Services, Medical Support and Compliance, and Medical Facilities accounts are appropriated in advance under 38 U.S.C. 117, so VA knows in one year what resources it will have in the following year. VA would use these figures to determine how it can enhance the value of the pharmacy portion of the medical benefits package by offering the maximum number of Tier 1 medications while maintaining the established budget parameters. VA does not anticipate dramatic changes in the numbers or types of medications that are available for a Tier 1 reduced copayment from year to year.

VA is aware that as a result of using these proposed criteria, some veterans who have conditions that are very serious but not very common may receive no Tier 1 medication copayment reduction under the proposed rule. Whether a particular veteran realizes reduced medication expenditures in a given year would depend on the medications VA selects for a reduced copayment amount and the medications prescribed to that veteran. However, as explained above, the purpose of this rule is to improve clinical outcomes for a large number of veterans while maintaining a responsible budget. VA does not expect that veterans' obligations for copayments would increase by a notable amount, and any increases resulting from this rule would be less than they would have been over time with the current regulations.

VA would also modify § 17.110(b)(3) to state that VA would publish a list of Tier 1 medications not less than once per year in the **Federal Register** and on VA's Web site at *www.va.gov/health*. The current paragraph (b)(3) requires VA to publish and distribute information on copayment amounts, but as these amounts would be established in regulation, there would be no need to continue that practice. VA expects it would publish a list of Tier 1 medications only once per year, but there may be situations when a change during the year would be justified. For example, if a medication that VA has

identified as a Tier 1 medication is removed from the market or if significant safety concerns are raised with its use, VA physicians and pharmacists would likely shift patients to a different multi-source medication to treat the same conditions. In this scenario, VA may elect to designate this alternative medication as a Tier 1 medication so that a large number of veterans do not experience a mid-year increase in the cost of filling their medications as a result of events outside their control.

VA has published a list of medications that it would classify as Tier 1 medications on its Web site, *www.va.gov/health.* This list was compiled using the process described above to show what medications would be placed in Tier 1 if the proposed rule were effective today, and as such, this list is intended to be demonstrative only. We expect the list of Tier 1 medications to change before January 1, 2017, as new medications become available, prices vary for different for medications, and new clinical evidence is published showing the efficacy of different medications. If the proposed rule is finalized and takes effect prior to January 1, 2017, VA will publish an updated list showing those medications that will be placed in Tier 1 for purposes of copayments starting on January 1, 2017.

VA would further modify § 17.110(b) by moving the discussion of the copayment cap from current paragraph (b)(2) to a new paragraph (b)(5). VA would amend this provision, which establishes a current rate and a methodology for increasing that rate, and replace it with a single rate that could only be changed through subsequent rulemaking. VA proposes to establish a fixed copayment cap of $700 in a calendar year for all enrolled veterans. VA is extending application of the copayment cap to include veterans in priority groups 7 and 8. A typical veteran fills two to three prescriptions per month, and at the current copayment rates, a veteran must fill 10 prescriptions per month each month of the year to hit the copayment cap. Presently, less than three percent of all veterans realize savings as a result of the copayment cap. With a copayment cap of $700, veterans filling six to eight prescriptions per month would likely reach the cap over a calendar year. Reducing the copayment cap would also provide a unique benefit to veterans who exclusively use Tier 3 medications, as their total annual expenses would be no more than $700, whereas under the current regulations, they would be $960 or more. We estimate approximately nine percent of veterans subject to a copayment would benefit from a $700 copayment cap. If, in the future, VA engaged in further rulemaking to raise the copayment rates from those proposed in this rule, it could also then consider whether to raise the copayment cap.

VA would also make a formatting revision to paragraph (b)(4), titling this section ''Veterans Choice Program,'' to maintain consistency with other paragraph headings. This would result in no formal or substantive change to the copayment rule articulated in this paragraph for the Veterans Choice Program, authorized by 38 CFR 17.1500–17.1540.

Effect of Rulemaking

The Code of Federal Regulations, if revised as proposed by this rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this rulemaking once made final, if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.''

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined that it is an economically significant regulatory action under Executive Order 12866.

Regulatory Impact Analysis Summary Statement

This rulemaking proposes to amend its regulations concerning copayments and the copayment cap charged to certain Veterans for medications required on an outpatient basis to treat non-service connected conditions. In addition, this rule would eliminate the formula used to calculate future rate increases and change the copayment amount beginning January 1, 2017, to $5 for a 30-day supply of Tier 1 medications, to $8 for a 30-day supply of Tier 2 medications, and $11 for a 30-day supply of Tier 3 medications. The Tiers of medications would be defined in regulation, but generally would reflect selected multi-source medications (Tier 1), other multi-source medications (Tier 2), and single source medications (Tier 3), with certain exceptions.

Based on a comparison of the current and proposed copayment amounts, we anticipate that most veterans would realize between a 10 and 50 percent reduction in their overall pharmacy copayment liability each year based on historic utilization patterns. By our estimates, 94 percent of copayment eligible veterans would experience no cost increase, and 80 percent would realize a savings of between $1 and $5 per 30-day equivalent of medications. The proposed copayment amounts are intended to support patient adherence, reduce instances of veterans not filling prescription medications and assisting veteran health improvements from chronic disease. Table 1 above, shows how copayments would vary for veterans and different types of medications. Annual savings would be even greater for veterans with a large number of medication copayments. VA estimates that at least 50 percent of all billable prescriptions would be in Tier 1, with no more than 35 percent in Tier 2, and approximately 15 percent in Tier 3. Exact estimates for Tier 1 and Tier 2

are not possible at this time and would depend on the final list of medications selected for Tier 1.

VA anticipates the implementation of a tiered copayment plan in CY2017 would reduce First Party Pharmacy copayment revenue from current budget levels for Veterans in PGs 2 through 8 who are required to make a copayment for certain medications. VA's regulatory impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at *http://www.va.gov/orpm/,* by following the link for ''VA Regulations Published From FY 2004 Through Fiscal Year to Date.''

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would generally be small business neutral. The rule would not affect pharmaceutical manufacturers, as it does not change the amount VA pays for medications to supply its pharmaceutical benefits program, only the amount VA collects from veterans as copayments. To the extent there are effects on pharmaceutical companies, we believe it would most likely have a positive affect if VA is purchasing more medications and supplies from them. Similarly, VA does not believe that this rule would have a significant economic impact on small pharmacies. It is possible that some veterans would choose to fill their prescriptions within VA rather than from a community pharmacist, but we anticipate such a shift would not result in a significant economic impact on a substantial number of such entities. Therefore, under 5 U.S.C. 605(b), this rulemaking would be exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Congressional Review Act

This proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been submitted to Congress and the Comptroller General for review.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.022, Veterans Home Based Primary Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, Department of Veterans Affairs, approved this document on September 1, 2015, for publication.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—Veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Dated: December 29, 2015.

William F. Russo,

Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

■ 2. Amend § 17.110 by:
■ a. Revising paragraph (a).
■ b. Revising paragraphs (b)(1)(i) through (iii).
■ c. Adding paragraph (b)(1)(iv).
■ d. Revising paragraphs (b)(2) and (3).
■ e. Adding a heading to paragraph (b)(4).
■ f. Adding paragraph (b)(5).

The revisions and additions read as follows:

§ 17.110 Copayments for medications.

(a) *General.* This section sets forth requirements regarding copayments for medications provided to veterans by VA. For purposes of this section, the term ''medication'' means prescription and over-the-counter medications, as determined by the Food and Drug Administration (FDA).

(b) * * *

(1) * * *

(i) For a 30-day or less supply of Tier 1 medications, the copayment amount is $5.

(ii) For a 30-day or less supply of Tier 2 medications, the copayment amount is $8.

(iii) For a 30-day or less supply of Tier 3 medications, the copayment amount is $11.

(iv) For purposes of this section:

(A) *Multi-source medication* is any one of the following:

(*1*) A medication that has been and remains approved by the FDA—

(*i*) Under sections 505(b)(2) or 505(j) of the Food, Drug, and Cosmetic Act (FDCA, 21 U.S.C. 355), and that has been granted an A-rating in the current version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book); or

(*ii*) Under section 351(k) of the Public Health Service Act (PHSA, 42 U.S.C. 262), and that has been granted an I or B rating in the current version of the FDA's Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (the Purple Book).

(*2*) A medication that—

(*i*) Has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a);

(*ii*) Which is referenced by at least one FDA-approved product that meets the criteria of paragraph (b)(1)(iv)(A)(*1*) of this section; and

(*iii*) Which is covered by a contracting strategy in place with pricing such that it is lower in cost than other generic sources.

(*3*) A medication that—

(*i*) Has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a); and

(*ii*) Has the same active ingredient or active ingredients, works in the same way and in a comparable amount of time, and is determined by VA to be substitutable for another medication that has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a). This may include but is not limited to insulin and levothyroxine.

(*4*) A listed drug, as defined in 21 CFR 314.3, that has been approved under FDCA section 505(c) and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

(B) *Tier 1 medication* means a multi-source medication that has been identified using the process described in paragraph (b)(2) of this section.

(C) *Tier 2 medication* means a multi-source medication that is not identified using the process described in paragraph (b)(2) of this section.

(D) *Tier 3 medication* means a medication approved by the FDA under a New Drug Application (NDA) or a biological product approved by the FDA pursuant to a biologics license agreement (BLA) that retains its patent protection and exclusivity and is not a multi-source medication identified in paragraph (b)(1)(iv)(A)(*3*) of this section.

(2) *Determining Tier 1 medications.* Not less than once per year, VA will identify a subset of multi-source medications as Tier 1 medications using the criteria below. Only medications that meet all of the criteria in paragraphs (b)(2)(i), (ii), and (iii) of this section will be eligible to be considered Tier 1 medications, and only those medications that meet all of the criteria in paragraph (b)(2)(i) of this section will be assessed using the criteria in paragraphs (b)(2)(ii) and (iii).

(i) A medication must meet all of the following criteria:

(A) The VA acquisition cost for the medication is less than or equal to $10 for a 30-day supply of medication;

(B) The medication is not a topical cream, a product used to treat musculoskeletal conditions, an antihistamine, or a steroid-containing medication;

(C) The medication is available on the VA National Formulary;

(D) The medication is not an antibiotic that is primarily used for short periods of time to treat infections; and

(E) The medication primarily is used to either treat or manage a chronic condition, or to reduce the risk of adverse health outcomes secondary to the chronic condition, for example, medications used to treat high blood pressure to reduce the risks of heart attack, stroke, and kidney failure. For purposes of this section, conditions that typically are known to persist for 3 months or more will be considered chronic.

(ii) The medication must be among the top 75 most commonly prescribed multi-source medications that meet the criteria in paragraph (b)(2)(i) of this section, based on the number of prescriptions issued for a 30-day or less supply on an outpatient basis during a fixed period of time.

(iii) VA must determine that the medication identified provides maximum clinical value consistent with budgetary resources.

(3) *Information on Tier 1 medications.* Not less than once per year, VA will publish a list of Tier 1 medications in the **Federal Register** and on VA's Web site at *www.va.gov/health*.

(4) *Veterans Choice Program.* * * * * * * * * *

(5) *Copayment cap.* The total amount of copayments in a calendar year for an enrolled veteran will not exceed $700.

* * * * *

[FR Doc. 2015–33052 Filed 1–4–16; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[WT Docket No. 15–285; FCC 15–155]

Improvements to Benchmarks and Related Requirements Governing Hearing Aid-Compatible Mobile Handsets

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks comment on revisions to the Commission's wireless hearing aid compatibility rules. The Commission proposes to adopt a consensus approach developed cooperatively by consumer advocates and industry trade associations, which would require manufacturers and service providers to increase the percentage of new wireless handset models that are hearing aid compatible over time, culminating in a system in which all wireless handset models are accessible to people with hearing loss.

DATES: Interested parties may file comments on or before January 14, 2016, and reply comments on or before January 29, 2016.

ADDRESSES: You may submit comments, identified by WT Docket No. 15–285; FCC 15–155, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://www.fcc.gov/cgb/ecfs/*. Follow the instructions for submitting comments.
- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- *People with Disabilities:* Contact the Commission to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *fcc504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

In addition to filing comments with the Secretary, a copy of any comments on the Paperwork Reduction Act information collection modifications proposed herein should be submitted to the Commission via email to *PRA@fcc.gov* and to Nicholas A. Fraser, Office of Management and Budget, via email to *Nicholas_A._Fraser@omb.eop.gov* or via fax at 202–395–5167.

FOR FURTHER INFORMATION CONTACT: For further information regarding the NPRM, contact Michael Rowan, Wireless Telecommunications Bureau, (202) 418–1883, email *Michael.Rowan@*