

values cited above, the Departments certify that this rulemaking will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

#### *Small Business Regulatory Enforcement Fairness Act*

Under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*), this proposed rule is not a major rule. It will not have an effect on the economy of \$100 million or more, will not cause a major increase in costs or prices for consumers, and will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

#### *Executive Order 12630*

Title VIII of ANILCA requires the Secretaries to administer a subsistence priority for rural Alaskan residents on public lands. The scope of this program is limited by definition to certain public lands. Likewise, these proposed regulations have no potential takings of private property implications as defined by Executive Order 12630.

#### *Unfunded Mandates Reform Act*

The Secretaries have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this rulemaking will not impose a cost of \$100 million or more in any given year on local or State governments or private entities. The implementation of this rule is by Federal agencies and there is no cost imposed on any State or local entities or tribal governments.

#### *Executive Order 12988*

The Secretaries have determined that these regulations meet the applicable standards provided in §§ 3(a) and 3(b)(2) of Executive Order 12988, regarding civil justice reform.

#### *Executive Order 13132*

In accordance with Executive Order 13132, the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Title VIII of ANILCA precludes the State from exercising subsistence management authority over fish and wildlife resources on Federal lands unless it meets certain requirements.

#### *Executive Order 13175*

Title VIII of ANILCA does not provide specific rights to tribes for the subsistence taking of wildlife, fish, and

shellfish. However, as described above under *Tribal Consultation and Comment*, the Secretaries, through the Board, will provide federally recognized Tribes and Alaska Native corporations an opportunity to consult on this proposed rule.

#### *Executive Order 13211*

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. However, this proposed rule is not a significant regulatory action under E.O. 13211, affecting energy supply, distribution, or use, and no Statement of Energy Effects is required.

#### **Drafting Information**

Theo Matuskowitz drafted this proposed rule under the guidance of Thomas C.J. Doolittle, Jr. of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional assistance was provided by:

- Daniel Sharp, Alaska State Office, Bureau of Land Management;
- Clarence Summers, Alaska Regional Office, National Park Service;
- Dr. Glenn Chen, Alaska Regional Office, Bureau of Indian Affairs;
- Carol Damberg, Alaska Regional Office, U.S. Fish and Wildlife Service; and
- Thomas Whitford, Alaska Regional Office, USDA—Forest Service.

#### **List of Subjects**

##### *36 CFR Part 242*

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

##### *50 CFR Part 100*

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

#### **Proposed Regulation Promulgation**

For the reasons set out in the preamble, the Federal Subsistence Board proposes to amend 36 CFR part 242 and 50 CFR part 100 for the 2020–21 and 2021–22 regulatory years.

■ The text of the proposed amendments to 36 CFR 242.24, 242.25, and 242.26 and 50 CFR 100.24, 100.25, and 100.26 is the final rule for the 2018–2020 regulatory periods for wildlife (83 FR 50759; October 9, 2018).

Dated: December 21, 2018.

**Thomas C.J. Doolittle,**

*Acting Assistant Regional Director, U.S. Fish and Wildlife Service.*

Dated: December 21, 2018.

**Thomas Whitford,**

*Subsistence Program Leader, USDA—Forest Service.*

[FR Doc. 2019–00424 Filed 1–30–19; 8:45 am]

**BILLING CODE 3411–15–4333–15–P**

## **DEPARTMENT OF VETERANS AFFAIRS**

### **38 CFR Part 17**

#### **RIN 2900–AQ47**

#### **Urgent Care**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) is proposing to amend its regulations that govern VA health care. This rule would grant eligible veterans access to urgent care from qualifying non-VA entities or providers without prior approval from VA. This rulemaking would implement the mandates of the VA MISSION Act of 2018 and increase veterans' access to health care in the community.

**DATES:** Comments must be received on or before March 4, 2019.

**ADDRESSES:** Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to: Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue, North West, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. (This is not a toll-free telephone number.) Comments should indicate that they are submitted in response to “RIN 2900–AQ47 Urgent Care.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 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 telephone 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:** Joseph Duran, Director of Policy and Planning, 3773 Cherry Creek North Drive, Denver, CO 80209. [Joseph.Duran2@va.gov](mailto:Joseph.Duran2@va.gov). (303) 370–1637. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** On June 6, 2018, section 105 of Public Law 115–182, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, or the VA MISSION Act of 2018, amended title 38 of the United States Code (U.S.C.) by adding a new section 1725A, Access to walk-in care. The new section 1725A was further amended through the Department of Veterans Affairs Expiring Authorities Act of 2018 (Pub. L. 115–251). This benefit is intended to offer eligible veterans convenient care for certain, limited, non-emergent health care needs. Section 1725A(a) and (g) direct the Secretary to establish procedures and regulations to ensure eligible veterans are able to access such care from qualifying non-VA entities or providers to ensure their access to care when minor injury or illness arises. VA is required to develop procedures to ensure eligible veterans are able to access this care from qualifying non-VA entities or providers. Eligible veterans would include any enrolled veteran who has received care under chapter 17 of title 38 United States Code (U.S.C.) within the 24-month period preceding the furnishing of care under this section. Care under chapter 17 of title 38, U.S.C., would include any of the following: Care provided in a VA facility, care authorized by VA performed by a community provider, care furnished by a State Veterans home, or urgent care under this proposed section. Qualifying non-VA entities or providers would include any non-VA entity or provider that has entered into a contract, agreement, or other arrangement with VA to provide services under this section.

VA proposes to refer to this benefit as urgent care, instead of walk-in care. As explained in further detail below, this benefit will include care provided at both urgent care facilities and walk-in retail health clinics. We believe referring to this type of care as “urgent care” would be consistent with industry practice.

This proposed rule would implement the mandates of section 1725A, as added by the VA MISSION Act of 2018 as amended, by establishing a new § 17.4600.

Proposed paragraph (a) would establish the purpose for this section. We would state that this section establishes procedures for accessing urgent care, which would be available to eligible veterans from qualifying non-VA entities or providers under the requirements established by this

rulemaking. This would be consistent with sections 1725A(a) and (g).

Proposed paragraph (b) would define the terms for this section. We would define the term “eligible veteran” in proposed paragraph (b)(1) as a veteran described in 38 U.S.C. 1725A(b). Section 1725A(b) defines eligible veterans as those who are enrolled under section 1705(a) of title 38, U.S.C. and who have received medical care under chapter 17 of title 38, U.S.C., within the 24-month period preceding the furnishing of urgent care under this new program. We would not restate the definition in section 1725A in the event that this section is amended in the future. As stated earlier, veterans have received care under chapter 17 of title 38, U.S.C., when they have received care provided in a VA facility, care authorized by VA and performed by a community provider, care furnished by a State Veterans home, or urgent care under this proposed section.

The term “episodic care” appears, but is not defined, in section 1725A(h). We propose to define the term “episodic care” in proposed paragraph (b)(2) as care or services provided to an eligible veteran for a particular health condition, or a limited set of particular health conditions, without an ongoing relationship being established between the eligible veteran and qualifying non-VA entities or providers. Episodic care would be only for a particular health condition (or a flu shot) or a limited set of particular health conditions, to be addressed in a single visit. For example, an eligible veteran could seek episodic care for a sore throat, an ankle sprain, or both in a single visit. There would be no further relationship between the qualifying non-VA entity or provider and the eligible veteran for the treatment of those health conditions. VA believes that flu shots, as well as therapeutic vaccines that are furnished in the course of treatment of another condition, would be clinically appropriate because the risk of an adverse reaction would be minimal for a flu shot, and therapeutic vaccines would be necessary for the treatment of certain conditions. For example, a veteran seeking treatment for a wound caused by rusted metal requires treatment for the wound and may require a tetanus vaccine as part of the course of treatment. VA acknowledges that there may be other preventive treatments with minimal risk of adverse action, however, VA considers these preventive care treatments to be part of the veteran’s longitudinal care, as such, these other treatments should be provided by the veteran’s primary care provider and not as part of urgent care.

As stated in section 1725A(h), urgent care should not be used for the longitudinal management of health care. These requirements are consistent with the general model of urgent care where patients seek health care for the treatment of minor injuries and illnesses through a single visit.

We propose to define the term “longitudinal management of conditions” in proposed paragraph (b)(3) as outpatient care that addresses important disease prevention and treatment goals and is dependent upon bidirectional communications that are ongoing over an extended period of time. Section 1725A(h) excludes from the definition of walk-in care the longitudinal management of conditions; while we would define the term “longitudinal management of conditions,” we would also state that, for purposes of this section, the term “longitudinal care” is synonymous with longitudinal management of conditions because we believe “longitudinal care” is better understood and would be clearer in the context of the regulation. We would only refer to outpatient care because urgent/walk-in care providers do not provide inpatient care or extended care services. The reference to bidirectional communications that are ongoing over an extended period of time is intended to reflect that longitudinal care occurs within the context of an ongoing relationship between the provider and patient.

Proposed paragraph (b)(4) would define the term “qualifying non-VA entities or providers” consistent with the definition in section 1725A(c), but we have specifically included Federally-qualified health centers based on section 1725A(d). We would define “qualifying non-VA entity or provider” as a non-VA entity or provider, including Federally-qualified health centers as defined in 42 U.S.C. 1396d(l)(2)(B), that has entered into a contract, agreement, or other arrangement with the Secretary to furnish urgent care under the section. VA currently furnishes care in the community through networks of providers that are maintained by third-party administrators. The third-party administrator meets the definition of the qualifying non-VA entity or provider—they are non-VA entities or providers that have entered into a contract or agreement with the Secretary to furnish care and services under this section—and it is through these administrators that the urgent care benefit primarily will be provided.

We propose to define the term “urgent care” in proposed paragraph (b)(5). This definition would include several key

conditions as follows. This definition would only apply to this section; other uses of the term “urgent care” or “urgent services” in other VA regulations, specifically §§ 17.101, 17.106, and 70.71, would not refer to this benefit. Section 1725A(h) defines the term “walk-in care” as non-emergent care provided by a qualifying non-Department entity or provider that furnishes episodic care and not longitudinal management of conditions and is otherwise defined through regulations the Secretary shall promulgate. However, VA proposes to use the term “urgent care” instead of “walk-in care.” Urgent care is an industry standard description of the services described below available at specific provider locations, including Federally Qualified Health Centers (FQHCs) as required under section 1725A(h). VA prefers to use an industry standard name for the benefit.

First, VA proposes to provide in proposed paragraph (b)(5) that urgent care is those services being provided by walk-in retail health clinics or urgent care facilities, as designated by the Centers for Medicare and Medicaid Services, furnished by a qualifying non-VA entity or provider, and as further defined in the paragraph. We believe that defining urgent care to include those services that are furnished by walk-in retail health clinics or urgent care facilities, as designated by the Centers for Medicare and Medicaid Services, would be in alignment with public expectations of the types of urgent care services that are otherwise available under other health care plans. The Centers for Medicare and Medicaid Services currently describes the services that walk-in retail health clinics and urgent care facilities furnish at the following website: [https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place\\_of\\_Service\\_Code\\_Set.html](https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html). VA’s proposed definition would also allow the benefit available under this section to evolve based upon advances in the industry regarding the types of services offered by these clinics and facilities. A qualifying non-VA entity or provider would have to enter into a contract, agreement, or other arrangement with VA to furnish services under this section. This is a requirement of section 1725A(c), and is also a critical part of the definition of a “qualifying non-VA entity or provider” under paragraph (b)(4). We note that, while we propose to define the scope of services available as urgent care in paragraph (b)(5), because of our reliance on contracts, agreements, or other arrangements, the

actual services available at a particular qualifying non-VA entity or provider may vary. We further note that any care that is provided to an eligible veteran that does not meet this definition, whether it be that the care was provided by a non-qualifying entity or provider or that the care provided was beyond the scope of urgent care as defined in this section, will not be covered by VA. In these situations, the eligible veteran would be liable for the cost of such care.

In proposed paragraph (b)(5)(i)(A), however, VA would not, except as provided for in paragraph (b)(5)(i)(B) or (b)(5)(iii), include preventive health services, as defined in 38 U.S.C. 1701(9). We would exclude generally preventive services because, consistent with the statutory requirement in section 1725A(e), the best way to ensure continuity of care is to have preventive health services coordinated and managed by a primary care provider furnishing longitudinal care. Section 1725A(e) requires that the Secretary ensure continuity of care for eligible veterans receiving this benefit. Preventive health services are a critical component to VA’s health care management system. VA believes that urgent care is fundamentally distinct from providing longitudinal health care within VA or the community. The best way to address a veteran’s health care needs would be to manage a veteran’s preventive health services as part of their overall health care rather than attempting to furnish such services on an episodic and uncoordinated basis. As such, we believe that to ensure continuity of care, as required by section 1725A(e), VA should exclude generally preventive health services from the definition of urgent care.

We would further define urgent care in proposed paragraph (b)(5)(i)(B) to include immunizations against influenza (flu shots), as well as therapeutic vaccines that are necessary in the course of treatment of an otherwise included service. Vaccinations are included within the definition of preventive health services in 38 U.S.C. 1701(9)(G) (which refers to immunizations) and as such would have been excluded under paragraph (b)(5)(i)(A).

We would also add in paragraph (b)(5)(ii) another requirement of urgent care: It must be furnished as “episodic care for eligible veterans needing immediate non-emergent medical attention, but does not include longitudinal care.” This is based on the definition of walk-in care in section 1725A(h).

Finally, we propose to state in paragraph (b)(5)(iii) that VA may

provide additional services it determines to be appropriate if it is in the interest of eligible veterans’, based on identified health needs. VA would inform the public via **Federal Register** document, published as soon as practicable, and other communication as VA determines appropriate. VA’s determination that additional services are in the interest of eligible veterans could be made to expand services regionally or nationally and for specified periods of time. This authority would only allow for the provision of services that qualifying non-VA entities or providers would otherwise furnish, but that would be excluded by our definition of the benefit of urgent care. Principally, these services would include preventive health services, including immunizations that are not for influenza or therapeutic vaccines. For example, if there is a localized outbreak of an infectious disease, VA could provide eligible veterans immunizations to prevent this disease as part of urgent care until the outbreak is contained.

Proposed paragraph (c) would establish procedures for urgent care. Procedures are required pursuant to section 1725A(a). We would state in proposed paragraph (c)(1) that eligible veterans may “receive urgent care from a qualifying non-VA entity or provider without prior approval from VA.” We believe this would be consistent with the general understanding of urgent and walk-in care, as well as the structure of the statute, which authorizes this benefit outside of the general Veterans Community Care Program under the amendments to section 1703, as made by section 101 of the VA MISSION Act of 2018. The general Veterans Community Care Program requires authorization for services, see amendments to section 1703(a)(3), while there is no similar requirement in section 1725A. This arrangement, combined with the Senate Committee’s report on this language, suggest that the purpose of this provision is to ensure that eligible veterans have access to convenient care. See S. Rpt. 115–212, p. 18.

We would provide in proposed paragraph (c)(2) that VA will publish a website containing information on urgent care, including the names, locations, and contact information for qualifying non-VA entities or providers within an eligible veteran’s community. The website would also include a list of services and other general information on the urgent care program established under this section.

Proposed paragraph (c)(3) would provide, in general, eligibility under the

section does not affect eligibility for hospital care or medical services under the medical benefits package, as defined in § 17.38, or other benefits addressed in title 38. Nothing in the section waives the eligibility requirements established in other statutes or regulations. This proposed paragraph would address the effect of urgent care on other provisions and programs administered by VA. Proposed paragraph (c)(3) would provide that, generally, eligibility for urgent care does not affect eligibility for hospital care or medical services under the medical benefits package or other benefits addressed in title 38. If particular services have unique eligibility standards, only veterans who are eligible under this section and who meet the eligibility standards for those services can elect to receive urgent care for them. Additionally, nothing in this section waives the eligibility requirements established in other statutes or regulations. However, eligibility for urgent care could affect eligibility for other benefits indirectly. For example, section 1725(b)(2)(B) provides that to be eligible for reimbursement for emergency treatment, a veteran must have received care under chapter 17 of title 38, U.S.C., within the 24-month period preceding the furnishing of such emergency treatment. If a veteran's only care within the 24-month period preceding the furnishing of such emergency treatment was for urgent care pursuant to these regulations, the veteran would satisfy this eligibility requirement and could be eligible for reimbursement for emergency treatment under section 1725.

Proposed paragraph (d) would establish the copayment obligations for eligible veterans. Section 1725A(f)(1)(A) authorizes the Secretary to require an eligible veteran to pay the United States a copayment for each episode of hospital care or medical services provided under the section if the eligible veteran would be required to pay a copayment under this title. Section 1725A(f)(1)(B) states that an eligible veteran not required to pay a copayment under the title may access walk-in care without a copayment for the first two visits in a calendar year. For any additional visits, a copayment at an amount determined by the Secretary may be required. Section 1725A(f)(1)(C) further states that an eligible veteran required to pay a copayment under the title may be required to pay a regular copayment for the first two walk-in care visits in a calendar year. For any additional visits, a higher copayment at an amount

determined by the Secretary may be required. Similarly, section 1725A(f)(2) states that after the first two episodes of care furnished to an eligible veteran under the section, the Secretary may adjust the copayment required of the veteran under the subsection based upon the priority group of enrollment of the eligible veteran, the number of episodes of care furnished to the eligible veteran during a year, and other factors the Secretary considers appropriate under the section.

In this rulemaking, we propose to establish a regular copayment for urgent care of \$30. An eligible veteran's liability for the \$30 regular copayment would depend on the veteran's enrollment category and the number of visits in a calendar year, as further explained below. We note that section 1725A(f)(3), which allows the Secretary to prescribe by rule the amount or amounts of copayments required under this section, allows the Secretary to establish unique regular copayments applicable to urgent care when provided under this section. We further note that section 1725A(f)(4) states that sections 8153(c) and 1703A(j) do not apply to section 1725A(f). Sections 8153(c) and 1703A(j) stipulate that care furnished pursuant to an agreement authorized by one of these sections is subject to the same terms as though provided in a facility of the Department, and that provisions of chapter 17 applicable to veterans receiving such care and services in a VA medical facility shall apply to veterans treated under this section. We interpret these exemptions, along with section 1725A(f)(3), to permit the Secretary to establish unique copayment amounts applicable to urgent care.

Copayments are a common feature of health care, including VA health care. They are an important mechanism for guiding behavior to ensure that patients receive care at an appropriate location. As previously stated in this rulemaking, urgent care does not include longitudinal care. Urgent care is considered to be a convenient option for care, but is not intended to be used as a substitute for traditional primary care. Also, collecting copayments allows VA to utilize its health care resources more efficiently.

VA believes that \$30 amount is consistent with the copayments charged by other Federal programs for similar benefits under the TRICARE and Medicare programs. Also, the \$30 amount is a reasonable charge because it is considerably less than what is commercially available, which on average is approximately \$67, based on an analysis VA conducted of private

sector benefits under commercial health plans. This amount is consistent with legislative history suggesting that the copayment amount not exceed \$50 per visit. S. Rpt. 115-212, p. 19. We believe that the convenience associated with accessing urgent care merits a copayment amount that could be higher than the amount that would apply if VA furnished that care in a VA facility or through authorized community care. Eligible veterans would not owe copayments at the time of service, consistent with current practice for VA and VA-authorized community care.

Consistent with section 1725A(f)(1)(B), we propose to require all eligible veterans who are enrolled in priority groups 1-6, except those veterans described in § 17.36(d)(3)(iii), to only pay the \$30 copayment after three urgent care visits. For further information on priority groups see § 17.36. Although these veterans are not required to pay copayments for other health care services furnished or paid for by VA, section 1725A(f)(1)(B) authorizes VA to start requiring a copayment after two visits, we believe that is appropriate to require a copayment after three visits instead of two. For those veterans who are enrolled in priority groups 7-8, including those veterans described in § 17.36(d)(3)(iii), we propose to charge the \$30 for all visits and will not exercise the authority under section 1725A(f)(1)(C) and (f)(2) to increase their copayment rate after two visits.

Therefore, we would state in proposed paragraph (d)(1) that, except as provided in paragraph (d)(2) or (d)(3), an eligible veteran, as a condition for receiving urgent care provided by VA under this section, must agree to pay VA (and is obligated to pay VA) a copayment of \$30 if the veteran is enrolled in priority groups 1-6, except those veterans described in § 17.36(d)(3)(iii) and has more than three urgent care visits under this section in a year, or if the veteran is enrolled in priority groups 7-8, including those veterans described in § 17.36(d)(3)(iii). These conditions would be stated in proposed paragraph (d)(1)(i), dealing with veterans enrolled in priority groups 1-6 generally, and in proposed paragraph (d)(1)(ii), dealing with veterans enrolled in priority groups 7-8.

Proposed paragraph (d)(2) would provide that an eligible veteran who receives urgent care under § 17.4600(b)(5)(iii) or urgent care consisting solely of an immunization against influenza (flu shot) is not subject to a copayment under paragraph (d)(1). VA would not charge a copayment for

flu shots to be consistent with private care best practice standards and be in alignment with other Federal programs. The Affordable Care Act requires health insurers to cover the flu shot without charging a copayment or coinsurance. While the insurer can require an individual to go to a specific facility to receive a flu shot, most insurers allow individuals to go to walk-in clinics for this benefit. Additionally, neither Medicare nor TRICARE charges a copayment for the flu shot. If VA were to charge a copayment for flu shots, we would not be aligned with the private sector or other government agencies. Furthermore, VA does not currently require a copayment for a flu shot if veterans receive one at a VA clinic on a walk-in basis, and we believe it is in the veterans' best interest to continue this practice.

Proposed paragraph (d)(3) would provide that if an eligible veteran receives more than one type of care on the same day that would subject the veteran to a copayment under § 17.108, which establishes copayments for inpatient and outpatient care, or § 17.111, which establishes copayments for extended care services, VA would only charge the higher copayment for that day. We would only charge one copayment to reduce the burden on the part of the eligible veteran. This is consistent with how VA charges copayments for multiple VA visits in the same day. See § 17.108(c)(2) and (f). VA would also only charge a single copayment if an eligible veteran receives more than one episode of care under § 17.4600 on the same day.

VA also proposes to amend § 17.105 to reflect the copayments as established in this rulemaking. First, VA would propose to include proposed § 17.4600 among the list of regulatory authorities under which copayments would be subject to a waiver under § 17.105(c). This would ensure that urgent care copayments would be treated the same as other copayments for eligible veterans seeking a waiver of their liability. Second, VA would delete the list of authorities for § 17.105 to comply with the guidelines of the Office of the Federal Register, but would add the complete list of authorities for this regulation, including 38 U.S.C. 1725A, among the authority citations listed for part 17.

VA similarly proposes to amend § 17.108(e) to make clear that the copayment exemptions for outpatient medical care specified in that section also apply to urgent care under this section. This would ensure consistent application of copayment rules for eligible veterans. We would make

similar conforming changes regarding the list of authorities for § 17.108.

#### **Effect of Rulemaking**

The Code of Federal Regulations, as proposed to be revised by this proposed 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 proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

#### **Paperwork Reduction Act**

This rulemaking does not contain any provisions constituting collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

#### **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 not have a significant economic impact on qualifying non-VA entities or providers. To the extent there is any such impact, it would result in increased business and revenue for them. We also do not believe there will be a significant economic impact on insurance companies, as claims would only be submitted for care that would otherwise have been received whether such care was authorized under this Program or not. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

#### **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,” which requires 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 the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and determined that the action is an economically significant regulatory action under Executive Order 12866. 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 regulatory impact analysis are available on VA's website at <http://www.va.gov/orpm> by following the link for VA Regulations Published from FY 2004 through FYTD.

Executive Order 12866 also directs agencies to “in most cases . . . include a comment period of not less than 60 days.” This regulation will increase access to care for eligible veterans in local communities across the country. Providing a 30-day comment period will allow the Secretary to expedite the commencement of this new benefit thereby increasing access to health care for eligible veterans. Moreover, we believe that urgent care is a common benefit among other health care plans and thus should not be an unfamiliar benefit to the public. Given general public familiarity with this benefit, we believe that 30 days would be a sufficient period of time for the public to comment on this rulemaking. In sum, providing a 60-day public comment period instead of a 30-day public comment period would be against public interest and the health and safety of eligible veterans. For the above reasons, the Secretary issues this rule with a 30-day public comment period. VA will consider and address comments that are received within 30 days of the date this proposed rule is published in the **Federal Register**.

**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 as follows: 64.009, Veterans Medical Care Benefits; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; and 64.018, Sharing Specialized Medical Resources.

**List of Subjects in 38 CFR Part 17**

Administrative practice and procedure, Claims, Day care, Dental health, Government contracts, Health care, Health facilities, Health professions, Health records, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

**Signing Authority**

The Secretary of Veterans Affairs 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. Wilkie, Secretary, Department of Veterans Affairs, approved this document on November 9, 2018, for publication.

Dated: January 25, 2019.

**Consuela Benjamin,**

*Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.*

For the reasons set forth in the preamble, we propose to amend 38 CFR part 17 as follows:

**PART 17—MEDICAL**

■ 1. The authority citation for part 17 is amended by adding entries for §§ 17.105, 17.108, and 17.4600 to read in part as follows:

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

\* \* \* \* \*

Section 17.105 is also issued under 38 U.S.C. 501, 1721, 1722A, 1724, and 1725A.

Section 17.108 is also issued under 38 U.S.C. 501, 1710, 1725A, 1730A, Sec. 101, Pub. L. 113–146, 128 Stat. 1754.

\* \* \* \* \*

Section 17.4600 is also issued under 38 U.S.C. 1725A.

**§ 17.105 [Amended]**

■ 2. Amend § 17.105 by:  
■ a. In paragraph (c), removing “or 17.111” and adding in its place “17.111, or 17.4600”.

■ b. Removing the authority citation at the end of the section.

■ 3. Amend § 17.108 by:

■ a. Revising paragraph (e) introductory text.

■ b. Removing the authority citation at the end of the section.

The revision reads as follows:

**§ 17.108 Copayments for inpatient hospital care and outpatient medical care.**

\* \* \* \* \*

(e) *Services not subject to copayment requirements for inpatient hospital care, outpatient medical care, or urgent care.* The following are not subject to the copayment requirements under this section or § 17.4600.

\* \* \* \* \*

■ 4. Add § 17.4600 to read as follows:

**§ 17.4600 Urgent care.**

(a) *Purpose.* The purpose of this section is to establish procedures for accessing urgent care. Eligible veterans may obtain urgent care from qualifying non-VA entities or providers under these requirements.

(b) *Definitions.* The following definitions apply to this section.

(1) *Eligible veteran* means a veteran described in 38 U.S.C. 1725A(b).

(2) *Episodic care* means care or services provided to an eligible veteran for a particular health condition, or a limited set of particular health conditions, without an ongoing relationship being established between the eligible veteran and qualifying non-VA entities or providers.

(3) *Longitudinal management of conditions* means outpatient care that addresses important disease prevention and treatment goals and is dependent upon bidirectional communications that are ongoing over an extended period of time. For purposes of this section, the term “longitudinal management of conditions” and “longitudinal care” are synonymous.

(4) *Qualifying non-VA entity or provider* means a non-VA entity or provider, including Federally-qualified health centers as defined in 42 U.S.C. 1396d(l)(2)(B), that has entered into a contract, agreement, or other arrangement with the Secretary to furnish urgent care under this section.

(5) *Urgent care* means those services being provided by walk-in retail health clinics or urgent care facilities, as designated by the Centers for Medicare and Medicaid Services, furnished by a qualifying non-VA entity or provider, and as further defined in paragraphs (b)(5)(i) through (iii) of this section.

(i)(A) Except as provided in paragraph (b)(5)(i)(B) or (b)(5)(iii) of this section, urgent care does not include preventive health services, as defined in section 1701(9) of title 38, United States Code.

(B) Urgent care includes immunization against influenza (flu shots), as well as therapeutic vaccines that are necessary in the course of treatment of an otherwise included service.

(ii) Urgent care may only be furnished as episodic care for eligible veterans needing immediate non-emergent medical attention, but does not include longitudinal care.

(iii) If VA determines that the provision of additional services is in the interest of eligible veterans, based upon identified health needs, VA may offer such additional services under this section as VA determines appropriate. Such services may be limited in duration and location. VA will inform the public through a **Federal Register** document, published as soon as practicable, and other communications, as appropriate.

(c) *Procedures.* (1) Eligible veterans may receive urgent care from a qualifying non-VA entity or provider without prior approval from VA.

(2) VA will publish a website containing information on urgent care, including the names, locations, and contact information for qualifying non-VA entities or providers.

(3) In general, eligibility under this section does not affect eligibility for hospital care or medical services under the medical benefits package, as defined in § 17.38, or other benefits addressed in this title. Nothing in this section waives the eligibility requirements established in other statutes or regulations.

(d) *Copayment.* (1) Except as provided in paragraphs (d)(2) and (3) of this section, an eligible veteran, as a condition for receiving urgent care provided by VA under this section, must agree to pay VA (and is obligated to pay VA) a copayment of \$30:

(i) After three visits in a calendar year if such eligible veteran is enrolled under § 17.36(b)(1) through (6), except those veterans described in § 17.36(d)(3)(iii) for all matters not covered by priority category 6.

(ii) If such eligible veteran is enrolled under § 17.36(b)(7) or (8), including veterans described in § 17.36(d)(3)(iii).

(2) An eligible veteran who receives urgent care under paragraph (b)(5)(iii) of this section or urgent care consisting solely of an immunization against influenza (flu shot) is not subject to a copayment under paragraph (d)(1) of this section.

(3) If an eligible veteran would be required to pay more than one copayment under this section, or a copayment under this section and a copayment under § 17.108 or § 17.111, on the same day, the eligible veteran will only be charged the higher copayment.

[FR Doc. 2019-00277 Filed 1-30-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Part 162

[CMS-0055-P]

RIN 0938-AT52

### Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would adopt a modification to the requirements for the use of the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs by requiring covered entities to use the Quantity Prescribed (460-ET) field for retail pharmacy transactions for Schedule II drugs. The modification would enable covered entities to clearly distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill, in the HIPAA retail pharmacy transactions. We believe this modification is important to ensure information is available to help prevent impermissible refills of Schedule II drugs, which would help to address the public health concerns associated with prescription drug abuse in the United States.

**DATES: Comment Date:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. April 1, 2019.

**ADDRESSES:** In commenting, please refer to file code CMS-0055-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0055-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0055-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

**FOR FURTHER INFORMATION CONTACT:**

Geanelle G. Herring, (410) 786-4466. Daniel Kalwa, (410) 786-1352. Angelo Pardo, (410) 786-1836.

**SUPPLEMENTARY INFORMATION: Inspection of Public Comments:** All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

### I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the Department of Health and Human Services (HHS) to adopt standards for electronic health care administrative transactions conducted between health care providers, health plans, and health care clearinghouses. In January 2009 (74 FR 3295), the Secretary adopted the National Council of Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide,

Version D, Release 0, August 2007 (hereinafter referred to as Version D.0) for the following retail pharmacy transactions: Health care claims or equivalent encounter information; referral certification and authorization; and coordination of benefits. As discussed later, a technical issue with Version D.0 necessitates a modification of the requirements for the use of this standard.

### A. Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills

The HHS Office of the Inspector General (OIG) conducted a study of Medicare Part D payments for Schedule II drugs that were billed as refills in 2009. Schedule II drugs are of particular interest to regulators because of the public health issues associated with their use and the potential for misuse and abuse. Schedule II drugs are defined, in part, by the Controlled Substances Act (CSA) as those with a high potential for abuse, with use potentially leading to severe psychological or physical dependence (21 U.S.C. 812(b)(2)). The CSA prohibits the refilling of Schedule II drugs; however, in some cases partial fills are permissible. Partial fills of Schedule II drugs were previously allowed only in limited circumstances, including where a pharmacist had less quantity on hand than the prescribed amount of medication, the prescription was for a patient in a LTC facility, or a patient had a terminal illness.<sup>1</sup>

Based on the data from the study, the HHS OIG issued a report in September 2012 titled “Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills,” which analyzed all of the 2009 program year prescription drug event (PDE) records for refills of Schedule II drugs.<sup>2</sup> The OIG analyzed 20.1 million records for Schedule II drugs and identified refills according to the numeric values in a particular data field—the Fill Number (403-D3)<sup>3</sup> field. The OIG concluded that the Medicare Part D program had inappropriately paid \$25 million for 397,203 Schedule II drug refills and that long-term care

<sup>1</sup> The Drug Enforcement Agency (DEA) indicated in a July 2017 letter to the NCPDP that it was currently promulgating proposed rulemaking to address the changes to 21 CFR 1306.13 (which concerns partial fills of prescriptions for Schedule II controlled substances) made by CARA.

<sup>2</sup> Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

<sup>3</sup> National Council of Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007, defines the Fill Number Field as “403-D3”.