Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–2727 for ''Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet Norden, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1127.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 15, 2018, FDA published a proposed rule with a 60-day comment period to implement the statutory changes made to the Federal Food, Drug, and Cosmetic Act by section 3024 of the 21st Century Cures Act (Pub. L. 114–255) to allow for a waiver or alteration of informed consent when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The proposed rule, if finalized, would permit an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain minimal risk clinical investigations. Comments on the proposed rule will inform FDA's rulemaking to establish regulations for IRB waiver or alteration of informed consent for certain minimal risk clinical investigations.

The Agency has received a request for a 60-day extension of the comment period for the proposed rule. This request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the request and is extending the comment period for the proposed rule for 30 days, until February 13, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: December 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27519 Filed 12–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2018–HA–0028]

RIN 0720–AB72

TRICARE; Addition of Physical Therapy Assistants and Occupational Therapy Assistants as TRICARE-Authorized Providers

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The Department of Defense is publishing this proposed rule to add certified or licensed physical therapy assistants (PTAs) and occupational therapy assistants (OTAs) as TRICARE-authorized providers to engage in physical therapy or occupational therapy under the supervision of a TRICARE-authorized physical therapist or occupational therapist in accordance with Medicare's rules for supervision and qualification when billed by under the supervising therapist's national provider identification number. This rule will align TRICARE with Medicare's policy, which permits PTAs or OTAs to provide physical or occupational therapy when supervised by and billed under a licensed or certified physical therapist or occupational therapist.

DATES: Written comments received at the address indicated in the **ADDRESSES** section by February 19, 2019 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, by either of the following methods:

• *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any

personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Erica Ferron, Defense Health Agency, Medical Benefits and Reimbursement Division, 303–676–3626 or *erica.c.ferron.civ@mail.mil.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Overview

A. Purpose of the Proposed Rule

This proposed rule implements section 721 of the National Defense Authorization Act for Fiscal Year 2018 (NDAA–18), and advances two of the components of the Military Health System's quadruple aim of improved readiness and better health. The TRICARE Basic benefit currently includes physical therapy (PT) and occupational therapy (OT) services rendered by TRICARE-authorized providers within the scope of their license when prescribed and monitored by a physician, certified physician assistant, or certified nurse practitioner. Allowing authorized physical therapists and occupational therapists to include as covered services those services of qualified assistants performing under their supervision may increase access to PT and OT services, and increase beneficiary choice in provider selection. Physical therapists and occupational therapists will be available to attend to more complex tasks for TRICARE beneficiaries, delegating to assistants simpler tasks for which they are licensed or certified to carry out. Adding coverage of services by authorized therapy assistants increases access at the same time the Agency anticipates that an active and aging beneficiary population will increasingly use these services.

B. Summary of the Major Provisions of the Proposed Rule

The major provisions of the proposed rule are:

➢ The addition of licensed or certified PTAs as TRICARE-authorized providers, operating under the same qualifications established by Medicare (42 Code of Federal Regulations (CFR) 484.4). Services must be furnished under the supervision of and billed by a licensed or certified TRICARE-authorized physical therapist.

➢ The addition of licensed or certified OTAs as TRICARE-authorized providers, operating under the same qualifications established by Medicare (42 CFR 484.4). Services must be furnished under the supervision of and billed by a licensed or certified TRICARE-authorized occupational therapist.

C. Costs and Benefits

PT and OT services are covered benefits of the TRICARE program, authorized at 32 CFR 199.4. We estimate that as a result of this rule, there will be a one-percent increase in the use of PT and OT services. The cost of increased utilization, along with first-year implementation costs of $350,000, is estimated at $20 million over five years.

The financial effect of this rule is not in the nature of economic costs or imposition of private expenditures to comply with Federal regulations. Rather, the rule involves fairly modest changes in federal health benefits payments. Consistent with OMB Circular A–4, such economic effects are considered ''transfer payments'' caused by Federal budget action, rather than regulatory benefits or costs that require additional analysis.

II. Discussion of Proposed Rule

A. Introduction and Background

Title 32 CFR 199.4(c)(3)(x) states that assessment and treatment services of a TRICARE authorized physical therapist or occupational therapist may be cost-shared under certain conditions when prescribed and monitored by a physician, certified physician assistant, or certified nurse practitioner. In addition, 32 CFR 199.6(c)(3)(iii)(K)(*2*) recognizes licensed registered physical therapists and licensed registered occupational therapists as TRICARE authorized providers when PT and OT services meet the conditions and are prescribed and monitored as described in the previous sentence. This rule proposes to extend coverage of PT and OT services, as required by NDAA–18, to include services provided by licensed or certified physical or occupational therapy assistants operating under the supervision of a TRICARE-authorized physical therapist or occupational therapist.

PTAs—Qualifications

PTAs typically hold an associate's degree in physical therapy and provide therapeutic interventions such as posture stabilization and therapeutic massage, but may not evaluate patients or create or alter treatment plans. This rule proposes to tie the qualifications of PTAs under the TRICARE program to Medicare's requirements as codified at 42 CFR 484.4.

PTAs—Supervision Requirements

Under this rule, TRICARE's supervision requirements match Medicare's. The DHA intends, in implementing instructions, to follow Medicare's requirements as found within Medicare's Benefit Policy Chapter 15.6 Part C and other issuances regarding supervision of PTAs. Direct supervision (*i.e.,* the supervising physical therapist is in the room with the PTA) will be required in a private practice setting, whereas general supervision (*i.e.,* the supervising physical therapist is not present but is available and remains responsible for the course of treatment) will be required in most other instances. In cases of general supervision, the supervising physical therapist will be required to make an onsite supervisory visit at least once every 30 days. In cases where state or local supervision laws are more stringent, the DHA will require physical therapists and the PTAs they supervise to follow state or local laws. Services provided by physical therapy aides or other personnel, even if under the supervision of a qualified physical therapist or physical therapy assistant, are not covered. Services provided by PTAs incident to services provided by physicians or other licensed or qualified providers other than physical therapists are not covered, as only physical therapists can supervise PTAs. If Medicare makes changes to its supervision requirements, the DHA will evaluate the changes and determine whether to make similar changes; any changes deemed appropriate shall be added to the implementing instructions.

PTAs—Reimbursement Requirements

This rule proposes to require services provided by the TRICARE-authorized PTA to be billed under the TRICARE-authorized supervising physical therapist's provider identification (ID). The DHA intends, in implementing instructions, to follow Medicare's requirements as found within Medicare's Benefit Policy Chapter 15.6 Part C and other issuances regarding reimbursement of services provided by PTAs. Services provided by a PTA above the skill-level of a PTA shall not be reimbursed. This includes, but is not limited to, evaluations and re-evaluations. Services provided by a PTA beyond the scope permitted by state or local law shall not be reimbursed.

OTAs—Qualifications

Occupational therapy assistants (OTAs) typically hold an associate's degree in occupational therapy and provide therapeutic interventions such as assisting in the development of motor skills in children with developmental disabilities or aiding adults in overcoming work-related injuries. OTAs may not evaluate patients or create or alter treatment plans. This rule proposes to tie the qualifications of OTAs under the TRICARE program to Medicare's

requirements as codified at 42 CFR 484.4.

OTAs—Supervision Requirements

Under this proposed rule, TRICARE's supervision requirements match Medicare's. The DHA intends, in implementing instructions, to follow Medicare's requirements as found within Medicare's Benefit Policy Chapter 15.6 Part C and other issuances regarding supervision of OTAs. Direct supervision (*i.e.,* the supervising occupational therapist is in the room with the OTA) will be required in a private practice setting, whereas general supervision (*i.e.,* the supervising occupational therapist is not present but is available and remains responsible for the course of treatment) will be required in most other instances. In cases of general supervision, the supervising occupational therapist will be required to make an onsite supervisory visit at least once every 30 days. In cases where state or local supervision laws are more stringent, the DHA will require occupational therapists and the OTAs they supervise to follow state or local laws. Services provided by occupational therapy aides or other personnel, even if under the supervision of a qualified occupational therapist or occupational therapy assistant, are not covered. Services provided by OTAs incident to services provided by physicians or other licensed or qualified providers other than occupational therapists are not covered, as only occupational therapists can supervise OTAs. If Medicare makes changes to its supervision requirements, the DHA will evaluate the changes and determine whether to make similar changes; any changes deemed appropriate shall be added to the implementing instructions.

OTAs—Reimbursement Requirements

This rule proposes to require services provided by a TRICARE-authorized OTA to be billed under the TRICARE-authorized supervising occupational therapist's provider ID. The DHA intends, in implementing instructions, to follow Medicare's requirements as found within Medicare's Benefit Policy Chapter 15.6 Part C and other issuances regarding reimbursement of services provided by OTAs. Services provided by an OTA above the skill-level of an OTA shall not be reimbursed. This includes, but is not limited to, evaluations and re-evaluations. Services provided by an OTA beyond the scope permitted by state or local law shall not be reimbursed.

Updated Referral Definition

In order to fully implement section 721 of the NDAA for 2018, DHA is updating the definition of referrals to remove the limitation that only physicians can make referrals and to distinguish between necessary referrals for general benefit coverage and referrals required under TRICARE Prime for Prime enrollee care. All referral requirements are provided in the regulations and in the implementing instructions.

III. Regulatory Procedures

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

E.O.s 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year).

We estimate that the effects of the provisions that would be implemented by this proposed rule would have an impact of approximately $20 million over five years. As a result, this rule is not significant and is not a major rule under the Congressional Review Act.

Executive Order (E.O.) 13771, ''Reducing Regulation and Controlling Regulatory Costs''

E.O. 13771 seeks to control costs associated with the government imposition of private expenditures required to comply with Federal regulations and to reduce regulations that impose such costs. Consistent with the analysis of transfer payments under OMB Circular A–4, this proposed rule does not involve regulatory costs subject to E.O. 13771.

Public Law 104–4, Section 202, ''Unfunded Mandates Reform Act''

Section 202 of Public Law 104–4, ''Unfunded Mandates Reform Act,'' requires that an analysis be performed to determine whether any federal mandate 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. The current threshold is approximately $140 million. We do not expect this proposed rule to result in any one-year expenditure that would meet or exceed this amount.

Public Law 96–354, ''Regulatory Flexibility Act'' (RFA) (5 U.S.C. 601)

Public Law 96–354, ''Regulatory Flexibility Act'' (RFA) (5 U.S.C. 601), requires that each Federal agency prepare a regulatory flexibility analysis when the agency issues a regulation which would have a significant impact on a substantial number of small entities. This proposed rule is not an economically significant regulatory action, and it has been certified that it will not have a significant impact on a substantial number of small entities. Therefore, this proposed rule is not subject to the requirements of the RFA.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This proposed rule does not contain a ''collection of information'' requirement, and does not impose additional information collection requirements on the public under Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35).

Executive Order 13132, ''Federalism''

E.O. 13132, ''Federalism,'' requires that an impact analysis be performed to determine whether the rule has federalism implications that would have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. It has been certified that this proposed rule does not have federalism implications, as set forth in E.O. 13132.

List of Subjects in 32 CFR Part 199

Administrative practice and procedure, Claims, Dental health, Fraud, Health care, Health insurance, Individuals with disabilities, Military personnel.

Accordingly, 32 CFR part 199 is amended as follows:

PART 199—[AMENDED]

■ 1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

■ 2. Section 199.2 is amended by revising the definition of ''referral.''

§ 199.2 Definitions.

* * * * *

Referral. The act or an instance of referring a TRICARE beneficiary to

another authorized provider to obtain necessary medical treatment. Generally, when a referral is required to qualify health care as a covered benefit, only a TRICARE-authorized physician may make such a referral unless this regulation specifically allows another category of TRICARE-authorized provider to make a referral as allowed within the scope of the provider's license. In addition to referrals which may be required for certain health care to be a covered TRICARE benefit, the TRICARE Prime program under § 199.17 generally requires Prime enrollees to obtain a referral for care through a primary care manager (PCM) or other authorized care coordinator to avoid paying higher deductible and cost-sharing for otherwise covered TRICARE benefits.

* * * * *

■ 3. Section 199.6 is amended by redesignating paragraph (c)(3)(iii)(K)(*2*)(*ii*) as paragraph (c)(3)(iii)(K)(*2*)(*iii*); revising paragraph (c)(3)(iii)(K)(*2*)(*i*); and adding a new paragraph (c)(3)(iii)(K)(*2*)(*ii*) to read as follows:

§ 199.6 TRICARE-authorized providers.

* * * * *

(c) * * *

(3) * * *

(iii) * * *

(K) * * *

(*2*) * * *

(*i*) Licensed registered physical therapist (PT), including a licensed or certified physical therapy assistant (PTA) performing under the supervision of a TRICARE-authorized PT. Services provided by a PTA shall be included in the fee of the supervising PT. PTAs shall meet the qualifications specified by Medicare (42 CFR 484.4) and the Director, DHA, shall issue policy adopting, to the extent practicable, Medicare's requirements for PTA supervision.

(*ii*) Licensed registered occupational therapist (OT), including a licensed or certified occupational therapy assistant (OTA) performing under the supervision of a TRICARE authorized OT. Services provided by an OTA shall be included in the fee of the supervising OT. OTAs shall meet the qualifications specified by Medicare (42 CFR 484.4) and the Director, DHA, shall issue policy adopting, to the extent practicable, Medicare's requirements for OTA supervision.

* * * * *

Dated: December 14, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–27508 Filed 12–19–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0131]

RIN 1625–AA09

Drawbridge Operation Regulation; Youngs Bay and Lewis and Clark River, Astoria, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the operating schedule that governs three bridges in Astoria, OR: The US101 New Youngs Bay highway bridge (New Youngs Bay Bridge), mile 0.7 crossing Youngs Bay; the Oregon State Old Youngs Bay highway bridge (Old Youngs Bay Bridge), mile 2.4, crossing Youngs Bay; and the Oregon State Lewis and Clark River highway bridge (Lewis and Clark River Bridge), mile 1.0, crossing the Lewis and Clark River. This NPRM will allow the bridge to open during weekend hours after receiving a 2 hour advance notice. The proposed modification will remove the draw tender during weekend hours due to minimal usage.

DATES: Comments and related material must reach the Coast Guard on or before January 22, 2019.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0131 using Federal eRulemaking Portal at *http://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email Steven M. Fischer, Bridge Administrator, Thirteenth Coast Guard District Bridge Program Office, telephone 206–220–7282; email *d13-pf-d13bridges@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
ODOT Oregon Department of Transportation
§ Section
U.S.C. United States Code

II. Background, Purpose and Legal Basis

The Coast Guard proposes revising the rule that governs three bridges at Astoria, OR, the New Youngs Bay Bridge, the Old Youngs Bay Bridge and the Lewis and Clark River Bridge. Due to infrequent drawbridge opening requests from Friday evenings through Monday early mornings, we propose opening the three highway bridges within Youngs Bay and Lewis and Clark River with a two-hour advance notice. The New Youngs Bay Bridge over five years had the most openings of 77 requests. We published a test deviation for six months in the **Federal Register** (83 FR 9430) on March 6, 2018, to collect data and comments for this proposed rule titled Drawbridge Operation Regulation; Youngs Bay and Lewis and Clark River. Only one comment was received, and that comment was not related to the schedule change for the test deviation. We did not receive any delay of opening complaints for the three subject bridges during the test deviation. The three bridges are operated by the Lewis and Clark River Bridge tender of the Oregon Department of Transportation (ODOT). Youngs Bay provides no alternate route to pass around the three subject bridges. The New Youngs Bay Bridge provides 39 feet of vertical clearance at mean high water, the Old Youngs Bay Bridge provides 24 feet of vertical clearance at mean high water, and the Lewis and Clark River Bridge provides 25 feet of vertical clearance at mean high water. The three subject bridges operate per 33 CFR 117.899 to open on signal if at least one half-hour notice is given to the draw tender at the Lewis and Clark River Bridge from 7 a.m. to 5 p.m. Monday through Friday, and from 8 a.m. to 4 p.m. on Saturday and Sunday. This proposed rule will allow the three subject bridges to open from Friday at 5 p.m. to Monday at 7 a.m. if at least a two-hour notice is given by telephone to the draw tender at the Lewis and Clark River Bridge. The purpose of this rulemaking is in regards to a request from ODOT to remove the bridge operator to reduce operating cost. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

This proposed rule amends 33 CFR 117.899 to provide specific requirements for the operation of the