

governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in any 1-year expenditure that meets or exceeds this amount.

FDA proposed the removal of § 558.15 on August 8, 2003, because it was obsolete or redundant. The original purpose of § 558.15 was to require the submission of the results of studies on the long-term administration of then-marketed antimicrobial drugs in animal feed on the occurrence of multiple drug-resistant bacteria associated with these animals. FDA determined that this section was obsolete as FDA had a new strategy and concept for assessing the safety of antimicrobial new animal drugs, including subtherapeutic use of antimicrobials in animal feed, with regard to their microbiological effects on bacteria of human health concern. This final rule removes the only remaining animal drug use listed in § 558.15(g), which is obsolete since approval of its NADA is now listed elsewhere in part 558.

Only one set of comments to the proposal was received by FDA. Since these comments did not question the benefits as described in the proposed rule, we retain the benefits for the final rule. This final rule is expected to provide greater clarity in the regulations for new animal drugs for use in animal feeds by deleting obsolete provisions in § 558.15. We do not expect this final rule to result in any direct human or animal health benefit. Rather, this final rule would remove regulations that are no longer necessary.

We do not expect the final rule that revokes the remaining portions of § 558.15 to have a substantive effect on any approved new animal drug or to cause any approved new animal drug to lose its marketing ability or experience a loss of sales.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget

under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

§ 558.4 [Amended]

■ 2. In paragraph (c) of § 558.4, remove “and in § 558.15 of this chapter”.

§ 558.15 [Removed]

■ 3. Remove § 558.15.

Dated: March 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-04945 Filed 3-4-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD-2014-HA-0133]

RIN 0720-AB62

TRICARE; Revision of Nonparticipating Providers Reimbursement Rate; Removal of Cost Share for Dental Sealants; TRICARE Dental Program

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This final rule revises the benefit payment provision for nonparticipating providers to more closely mirror industry practices by requiring TDP nonparticipating providers to be reimbursed (minus the appropriate cost-share) at the lesser of billed charges or the network maximum allowable charge for similar services in that same locality (region) or state. This rule also updates the regulatory provisions regarding dental sealants to clearly categorize them as a preventive service and, consequently, eliminate the current 20 percent cost-share applicable to sealants to conform with the language in the regulation to the statute.

DATES:

Effective date: The final rule is effective April 6, 2016.

Applicability date: The programmatic improvements in this final rule are scheduled to take effect as soon as the Director, Defense Health Agency can effectively and efficiently implement through award of a new TRICARE Dental Program contract. No change will be negotiated for existing contracts to implement this rule. Implementation through the new contract will be effective with the start of care delivery under the new contract (currently anticipated to start February 1, 2017).

FOR FURTHER INFORMATION CONTACT: Col James Honey, Defense Health Agency, telephone (703) 681-0039.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

1. Purpose of Regulatory Actions

a. Need for Regulatory Actions

(1) Revision of Nonparticipating Providers' Reimbursement Rate

Prior to 2006, TRICARE Dental Program (TDP) participating and nonparticipating providers were reimbursed at the equivalent of not less than the 50th percentile of prevailing charges made for similar services in the same locality (region) or state, or the provider's actual charge, whichever is lower, less any cost-share amount due for authorized services. This provision was included in the regulation to constitute a significant financial incentive for participation of providers in the contractor's network and to ensure a network of quality providers through use of a higher reimbursement rate. Over time, the Department discovered that this provision placed an unnecessary burden on contractors with already established, high quality provider networks with reimbursement rates below the 50th percentile that were of sufficient size to meet the access requirements of the TDP. Consequently, the Department of Defense published a final rule in the **Federal Register** on January 11, 2006 (71 FR 1695), revising the participating provider's reimbursement rate for the TDP that has resulted in significant cost savings to the TDP enrollees and the Government. Since over 80 percent of all TDP care was provided by network dentists, the need to also change the reimbursement rate for nonparticipating dentists was overlooked and not included in the 2006 rule change. However, over the past eight years this has created an incentive for some network providers to leave the TDP network and for other providers not to become network providers. As the rule is currently written, depending on the geographic location, some non-network providers

are actually reimbursed at a higher amount than they would have been had they been a participating provider and receiving the negotiated network rate. Specifically, the final rule will require TDP nonparticipating providers to be reimbursed (minus the appropriate cost-share) at the lesser of (1) billed charges; (2) the network maximum allowable charge for similar services in that same locality (region) or state. This revision will increase the number of network providers and provide cost savings to enrollees and the Government.

(2) Removal of Cost-Share for Dental Sealants

Sealants are currently separately defined in the TDP regulation at 32 CFR 199.13(b)(24), and specifically identified as a covered non-preventive service subject to a 20 percent cost-share. The cost-share for dental sealants was originally put in place when there was minimal evidence as to the effectiveness of dental sealants preventing tooth decay. The scientific evidence is now overwhelming that dental sealants are effective in preventing tooth decay and the vast majority of commercial dental insurance plans cover this procedure with no cost shares. Further, the American Dental Association's Council on Dental Care Programs Code on Dental Procedures and Nomenclature classifies dental sealants as a preventive procedure. Additionally, the Department currently recognizes sealants as a preventive service under the TRICARE Retiree Dental Program per 32 CFR 199.22(f)(1)(ii)(C). The regulatory revisions regarding dental sealants will delete the separate definition of dental sealants, specifically include sealants as a category of preventive service under 32 CFR 199.13(e)(2)(i)(B), delete any possible inconsistency in the definition of preventive service in 32 CFR 199.13(b)(20) and (e)(2)(i), and update the cost-share table in 32 CFR 199.13(e)(3)(i) to delete the specific line item reference to sealants being subject to a 20 percent cost-share in order to conform with the requirement in 10 U.S.C. 1076a(e)(1)(A) that TDP enrollees pay no charge for preventive services.

b. Legal Authority for the Regulatory Action

This regulation is finalized under the authority of 10 U.S.C. 1076a which authorizes the Secretary of Defense to establish a voluntary enrollment dental plan for eligible dependents of members of the uniformed services who are on active duty for a period of more than 30 days, members of the Selected Reserve of the Ready Reserve, members of the

Individual Ready Reserve, and eligible dependents of members of the Ready Reserve of the reserve components who are not on active duty for more than 30 days.

2. Summary of the Final Rule

In this final rule, the regulatory language changes nonparticipating provider (e.g. non-network or out-of-network) reimbursement at 32 CFR 199.13(g)(2)(i) to be on an equivalent basis with network reimbursement, in order to serve as an incentive for both providers to participate in the network and for beneficiaries to utilize network providers in order to avoid additional out-of-pocket costs for balance billing. The final rule includes several technical revisions for clarification and consistency sake in defining beneficiary liability, nonparticipating provider and participating provider in the context of the TDP. The final rule also amends several provisions within 32 CFR 199.13 to eliminate the separate definition of sealants, specifically include sealants as a covered preventive service, and remove beneficiary cost sharing by covering sealants at 100 percent of allowable charge as authorized by law.

3. Summary of the Costs and Benefits

This final rule is not anticipated to have an annual effect on the economy of \$100 million or more, making it a substantive, non-significant rule under the Executive Order and the Congressional Review Act. The amendment to transition nonparticipating provider reimbursement to be on an equivalent basis with network reimbursement, will result in (1) a lower allowed-to-billed ratio and a decrease in TDP claim payments, (2) premium decreases for beneficiaries; (3) a corresponding increase in enrollment by eligible beneficiaries as a result of these premium changes; (4) resultant cost savings to the government through reduced premium subsidies; and (5) increased out-of-pocket costs for beneficiaries who opt to use a nonparticipating provider who may balance bill for the difference in contractor payment at the current rates and the new, lower network agreement rates. While the requirements for sealant coverage will not change, the removal of beneficiary cost sharing for sealants will result in (1) a marginal increase in sealant utilization, as we anticipate most beneficiaries requiring sealants are currently receiving these services since they remain a relatively inexpensive procedure and are typically viewed as beneficial; (2) a minimal premium increase for beneficiaries; and (3) an

increase in government costs as a result of both the direct effect of the waived cost sharing on current sealant services and the full cost of the additional utilization. We estimate that the net effects of the TDP provisions that would be implemented by this rule would result in a net premium decrease for TDP beneficiaries and corresponding cost savings to the government over \$17 million per year as well as an anticipated increase in the number of participating network providers.

II. Background

1. Statutory and Regulatory Background

The TRICARE Dental Program (TDP) allows the Secretary of Defense to offer comprehensive premium based indemnity dental insurance coverage to qualified individuals. The funds used by the TDP are appropriated funds furnished by Congress through annual appropriation acts and funds collected as premium shares from beneficiaries. TDP is delivered through a competitively procured contract awarded by the Director, Defense Health Agency, or designee. TDP enrollees are required to pay all or a portion of the premium cost depending on their status. For those eligible for premium sharing, including active duty dependents and certain Selected Reserve and Individual Reserve members, the portion of premium share to be paid by them is no more than forty (40) percent of the total premium. For those entitled to premium sharing, the Government pays the remaining sixty (60) percent of the premium. Additional information regarding the TDP is available at www.tricare.mil/tdp.

Because the amendments to 32 CFR 199.13 will result in changes to the TDP voluntary enrollment dental insurance plan which is administered through a competitively procured contract, these amendments will be incorporated into the next TDP contract and are scheduled to take effect with the start of health care delivery under the next awarded TDP contract (currently anticipated to start February 1, 2017).

2. Summary of the Proposed Rule

We proposed several amendments to the TRICARE Dental Program (TDP) regulation. Specifically, we proposed revising the benefit payment provision for nonparticipating providers to more closely mirror industry practices by requiring TDP nonparticipating providers to be reimbursed (minus the appropriate cost-share) at the lesser of (1) billed charges; Or (2) the network maximum allowable charge for similar

services in that same locality (region) or state. This rule also proposed updates to the regulatory provisions regarding dental sealants to clearly categorize them as a preventive service and, consequently, eliminate the current 20 percent cost-share applicable to sealants to conform the language in the regulation to the statute.

3. Summary of the Final Rulemaking

The final rule changes the nonparticipating provider (e.g. non-network or out-of-network) reimbursement at 32 CFR 199.13(g)(2)(i) to be on an equivalent basis with network reimbursement, in order to serve as an incentive for both providers to participate in the network and for beneficiaries to utilize network providers in order to avoid additional out-of-pocket costs for balance billing. The final rule also eliminates the separate definition of sealants found at 32 CFR 199.13(b)(24) in favor of including it as a category of preventive service under 32 CFR 199.13(e)(2)(i)(B). Also, as a result of clearly classifying dental sealants as a preventive service, the final rule eliminates the current 20 percent cost-share to conform with the requirement in 10 U.S.C. 1076a(e)(1)(A) that TDP enrollees pay no charge for preventive services.

III. Summary of and Response to Public Comments

The proposed rule was published in the **Federal Register** (79 FR 78362) December 30, 2014, for a 60-day comment period. We received only one comment on the proposed rule applauding the proposed change to remove the 20 percent cost share for dental sealants. Because the comment supported the proposed changes, we are finalizing the proposed rule with no changes.

IV. Regulatory Procedures

Executive Order 12866, "Regulatory Planning and Review" and E.O. 13563, "Improving Regulation and Regulatory Review"

It has been determined that his final rule is not a significant regulatory action. This rule does not:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; completion; 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 Orders.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4)

It has been determined that this final rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

It has been certified that this final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Set forth in the final rule are minor revisions to the existing regulation. The DoD does not anticipate a significant impact on the Program.

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

It has been determined that this final rule will not impose additional reporting or recordkeeping requirements under the Paperwork Act of 1995. Existing information collections requirements of the TRICARE and Medicare programs will be utilized.

Executive Order 13132, Federalism

It has been determined that this final rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

- (1) The States;
 - (2) The relationship between the National Government and the States; or
- The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Dental sealants, 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 199.13 is amended by:

- a. Revising paragraphs (b)(4), (14), (17), and (20).
- b. Removing paragraph (b)(24).
- c. Revising paragraph (e)(2)(i) introductory text.
- d. Adding paragraph (e)(2)(i)(B)(5).
- e. Removing the entry entitled "Sealants" from the table following paragraph (e)(3)(i).
- f. Revising paragraphs (f)(5) and (g)(2)(i).

The revisions and additions read as follows:

§ 199.13 TRICARE Dental Program.

* * * * *

(b) * * *

(4) *Beneficiary liability.* The legal obligation of the beneficiary, his or her estate, or responsible family member to pay for the costs of dental care or treatment received. Specifically, for the purposes of services and supplies covered by the TDP, beneficiary liability including cost-sharing amounts or any amount above the network maximum allowable charge where the provider selected by the beneficiary is not a participating provider or a provider within an approved alternative delivery system. In cases where a nonparticipating provider does not accept assignment of benefits.

* * * * *

(14) *Nonparticipating provider.* A dentist or dental hygienist that furnished dental services to a TDP beneficiary, but who has not agreed to participate in the contractor's network and accept reimbursement in accordance with the contractor's network agreement. A nonparticipating provider looks to the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member for final responsibility for payment of his or her charge, but may accept payment (assignment of benefits) directly from the insurer or assist the beneficiary in filing the claim for reimbursement by the dental plan contractor. Where the nonparticipating provider does not accept payment directly from the insurer, the insurer pays the beneficiary or active duty, Selected Reserve or Individual Ready Reserve member, not the provider.

* * * * *

(17) *Participating provider.* A dentist or dental hygienist who has agreed to participate in the contractor's network and accept reimbursement in accordance with the contractor's network agreement as the total charge (even though less than the actual billed amount), including provision for payment to the provider by the beneficiary (or active duty, Selected

Reserve or Individual Ready Reserve member) or any cost-share for covered services.

* * * * *

(20) *Preventive services.* Traditional prophylaxis including scaling deposits from teeth, polishing teeth, and topical application of fluoride to teeth, as well as other dental services authorized in paragraph (e) of this section.

* * * * *

(e) * * *

(2) * * *

(i) Diagnostic and preventive services. Benefits may be extended for those dental services described as oral examination, diagnostic, and preventive services when performed directly by dentists and dental hygienists as authorized under paragraph (f) of this section. These include the following categories of service:

* * * * *

(B) * * *

(5) Sealants.

* * * * *

(f) * * *

(5) *Participating provider.* An authorized provider may elect to participate as a network provider in the dental plan contractor's network and any such election will apply to all TDP beneficiaries. The authorized provider may not participate on a claim-by-claim basis. The participating provider must agree to accept, within one (1) day of a request for appointment, beneficiaries in need of emergency palliative treatment. Payment to the participating provider is based on the methodology specified in paragraph (g)(2)(ii) of this section. The fee or charge determinations are binding upon the provider in accordance with the dental plan contractor's procedures for participation in the network. Payment is made directly to the participating provider, and the participating provider may only charge the beneficiary the applicable percent cost-share of the dental plan contractor's allowable charge for those benefit categories as specified in paragraph (e) of this section, in addition to the full charges for any services not authorized as benefits.

* * * * *

(g) * * *

(2) * * *

(i) Nonparticipating providers (or the beneficiaries or active duty, Selected Reserve or Individual Ready Reserve members for unassigned claims) shall be reimbursed at the lesser of the provider's actual charge: Or the network maximum allowable charge for similar services for that same locality (region) or state, whichever is lower, subject to the exception listed in paragraph (e)(3)(ii) of

this section, less any cost-share amount due for authorized services. The network maximum allowable charge is the maximum negotiated fee between the dental contractor and any TDP participating provider for similar services covered by the dental plan in that same locality (region) or state.

* * * * *

Dated: March 2, 2016.

Morgan E. Park,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016-04983 Filed 3-4-16; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2016-0150]

Drawbridge Operation Regulation; Hackensack River, Jersey City, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the PATH Bridge across the Hackensack River, mile 3.0, at Jersey City, New Jersey. This deviation is necessary to allow the bridge owner to replace rails and ties at the bridge. This deviation allows the bridge to remain closed on Saturdays through Mondays for twenty-six consecutive weekends.

DATES: This deviation is effective from 12:01 a.m. on March 19, 2016 to 12:01 a.m. on September 12, 2016.

ADDRESSES: The docket for this deviation, [USCG-2016-0150] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Joe M. Arca, Project Officer, First Coast Guard District, telephone (212) 514-4336, email joe.m.arca@uscg.mil.

SUPPLEMENTARY INFORMATION: The PATH railroad bridge across the Hackensack River, mile 3.0, at Jersey City, New Jersey, has a vertical clearance in the closed position of 40 feet at mean high water and 45 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.723.

The waterway is transited by seasonal recreational vessels and commercial vessels of various sizes.

The bridge owner, Port Authority Trans-Hudson (PATH), requested a temporary deviation from the normal operating schedule to facilitate replacement of the rails and ties at the bridge.

Under this temporary deviation, the PATH railroad bridge may remain in the closed position for twenty-six weekends, between 12:01 a.m. on Saturdays through 12:01 a.m. on Mondays from March 19, 2016 through September 12, 2016.

Vessels able to pass under the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 2, 2016.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2016-04994 Filed 3-4-16; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2015-0592; FRL-9943-15-Region 5]

Air Plan Approval; Minnesota; Revision to Visibility Federal Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is revising the Minnesota Federal implementation plan (FIP) for visibility, to establish emission limits for Northern States Power Company's (NSP's) Sherburne County Generating Station (Sherco), pursuant to a settlement agreement. The settlement