FDA to F. Ellison, Division of Petition Review, CFSAN, FDA, February 7, 2013.
11. Memorandum from A. Khan, Division of Petition Review, CFSAN, FDA to F. Ellison, Division of Petition Review, CFSAN, FDA, June 22, 2010.
12. Memorandum from T. Walker, Division of Petition Review, CFSAN, FDA to F. Ellison, Division of Petition Review, CFSAN, FDA, December 27, 2011.
13. Memorandum from I. Chen, Division of Petition Review, CFSAN, FDA to F. Ellison, Division of Petition Review, CFSAN, FDA, May 24, 2010.
14. Memorandum from S. Francke-Carroll and S. Mog, Senior Science and Policy Staff, CFSAN, FDA to C. Whiteside and A. Khan, Division of Petition Review, CFSAN, FDA, March 17, 2011.
15. Memorandum from A. Khan, Division of Petition Review, CFSAN, FDA to F. Ellison, Division of Petition Review, CFSAN, FDA, March 3, 2012.
16. CFSAN Cancer Assessment Committee Full Committee Review, Carcinogenicity Evaluation of Advantame, April 27, 2012.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Add § 172.803 to subpart I to read as follows:

§ 172.803 Advantame.

(a) Advantame is the chemical *N*-[*N*-[3-(3-hydroxy-4-methoxyphenyl)propyl]-α-aspartyl]-L-phenylalanine 1-methyl ester, monohydrate (CAS Reg. No. 714229–20–6).

(b) Advantame meets the following specifications when it is tested according to the methods described or referenced in the document entitled ''Specifications and Analytical Methods for Advantame'' dated April 1, 2009, by the Ajinomoto Co. Inc., Sweetener Department 15–1, Kyobashi 1-chome, Chuo-ku, Tokyo 104–8315, Japan. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(1) Assay for advantame, not less than 97.0 percent and not more than 102.0 percent on a dry basis.

(2) Free *N*-[*N*-[3-(3-hydroxy-4-methoxyphenyl)propyl]-α-aspartyl]-L-phenylalanine, not more than 1.0 percent.

(3) Total other related substances, not more than 1.5 percent.

(4) Lead, not more than 1.0 milligram per kilogram.

(5) Water, not more than 5.0 percent.

(6) Residue on ignition, not more than 0.2 percent.

(7) Specific rotation, determined at 20 °C $[\alpha]_D$: −45.0 to −38.0° calculated on a dry basis.

(c) The food additive advantame may be safely used as a sweetening agent and flavor enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice, in an amount not to exceed that reasonably required to achieve the intended technical effect, in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(d) If the food containing the additive purports to be or is represented to be for special dietary use, it must be labeled in compliance with part 105 of this chapter.

Dated: May 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11584 Filed 5–19–14; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[DOD–2012–OS–0105]

RIN 0720–AB58

32 CFR Part 199

TRICARE Revision to CHAMPUS DRG-Based Payment System, Pricing of Hospital Claims

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: This Final rule changes TRICARE's current regulatory provision for inpatient hospital claims priced under the DRG-based payment system. Claims are currently priced by using the rates and weights that are in effect on a beneficiary's date of admission. This Final rule changes that provision to price such claims by using the rates and weights that are in effect on a beneficiary's date of discharge.

DATES:

Effective Date: This Final rule is effective June 20, 2014.

Applicability Date: This rule applies to claims with a discharge date of October 1, 2014, or later from hospitals paid by TRICARE under the Inpatient Prospective Payment System/Diagnosis-Related Groups-based payment system.

FOR FURTHER INFORMATION CONTACT: Ms. Amber Butterfield, TRICARE Management Activity, Medical Benefits and Reimbursement Office, telephone (303) 676–3565.

SUPPLEMENTARY INFORMATION:

I. Dates

The effective date above is the date that the policies herein take effect and are considered to be officially adopted. The applicability date, which is different than the effective date, is the date on which the policies adopted in this rule shall apply to claims from hospitals paid by TRICARE under the Inpatient Prospective Payment System/Diagnosis-Related Groups-based payment system, and must be implemented.

II. Executive Summary and Overview

A. Purpose of the Final Rule

1. Need for the Regulatory Action

This Final rule amends the TRICARE/CHAMPUS regulatory provision (32 CFR 199.14(a)(1)(i)(C)(3)) of pricing inpatient hospital claims that are reimbursed under the DRG-based payment system from the beneficiary's date of admission, to pricing such

claims based on the beneficiary's date of discharge.

The TRICARE/CHAMPUS DRG-based payment system applies to acute care hospitals, unless such hospital is exempt by regulation from the payment system. Under the TRICARE DRG-based payment system, payment for the operating costs of inpatient hospital services subject to the payment system is made on the basis of prospectively determined rates.

The TRICARE DRG-based payment system is modeled on the Medicare Inpatient Prospective Payment System (IPPS). Although many of the procedures in the TRICARE DRG-based payment system are similar or identical to the procedures in the Medicare IPPS, the actual payment amounts, DRG weights, and certain procedures are different. This is necessary because of the differences in the two programs, especially in the beneficiary population.

Since the inception of the TRICARE DRG-based payment system in 1987, claims have been priced after the beneficiary's discharge by the hospital, but using the weights and rates that were in effect on the beneficiary's date of admission. That is, claims submitted for the beneficiary's inpatient stay have been grouped to a specific DRG, and the pricing (e.g., payment rate) has been determined by using the weights and rates that were in effect on the date of the beneficiary's admission to the hospital.

B. Summary of the Major Provisions of the Final Rule

The major provision of this rule is to revise TRICARE's regulation on the pricing of claims paid under the DRG-based payment system. Claims are currently priced by using the rates and weights that are in effect on a beneficiary's date of admission. This rule changes that provision to price such claims by using the rates and weights that are in effect on a beneficiary's date of discharge. The change shall apply to claims with a discharge date of October 1, 2014, or later from hospitals paid by TRICARE under the Inpatient Prospective Payment System/Diagnosis-Related Groups-based payment system.

C. Costs and Benefits

The benefits of this change include aligning TRICARE pricing of hospital claims practices with industry standards utilized by Medicare and other payers and thereby increasing standardization of claims administration and other claims related processes for contractors who adjudicate claims.

There are known costs associated with this change. On May 27, 2011, Kennell and Associates completed an Independent Government Cost Estimate (''May 27, 2011, IGCE'') analyzing the costs associated with the shift of pricing DRG claims from the date of admission to the date of discharge. The May 27, 2011, IGCE, identified three known costs.

1. One time information technology costs associated with changes to Managed Care Support Contractors' claims processing systems and one time administrative costs associated with the review change order and the assessment of the impact on Claims Operations, Customer Service, Provider Administration, and Contracts Maintenance. The total one time information technology and administrative costs for North, South, West and TDEFIC Managed Care Support Contractors' combined is estimated at $88,208.

2. An annual cost of reprocessing interim claims of $2,500.

3. An increase in health care costs to account for using the weights and rates in place on the date of discharge. The May 27, 2011, IGCE, using 2009 claims data, estimated about 1,200 inpatient claims will span fiscal years. Consequently, reimbursing using the updated weights and rates in place for the discharges in future fiscal years is expected to increase the payment for approximately 1,200 claims with an estimated additional cost of $500,000 annually.

4. Total costs for this change for Fiscal Year 2015 equal approximately $600,000.

III. Background

A. Statutory and Regulatory Overview

Sections 1073 and 1079 of title 10, United States Code (U.S.C.), authorize the Secretary of Defense to administer the medical and dental benefits provided under chapter 55 of title 10, and contract for medical care for specified persons. These sections and other provisions of 10 U.S.C. chapter 55 authorize promulgation of this Final rule.

The August 31, 1988, Final rule [53 FR 33461] (the ''August 1988 Final rule'') published in the **Federal Register** explains TRICARE's current practice of utilizing the date of admission to price claims. Using the date of admission to price claims allowed hospitals to be reimbursed for inpatient services under the same payment methodology they expected to be used when the patient was admitted. Prior to implementation of the DRG-based payment system, the hospital could expect to be reimbursed at the billed charge rate, since that was the method TRICARE used to reimburse hospitals at that time. For patients admitted after implementation of the DRG-based payment system, the hospital could expect to be reimbursed using the DRG-based payment system.

The August 1988 Final rule continues by stating that since certain services were previously excluded from the DRG-based system, but may have already involved an interim bill prior to the effective date of the August 1988 Final rule, it would be administratively difficult and fiscally unfair to hospitals to attempt to reconcile the total payments with the DRG-based allowed amounts. As a result of the analysis at the time, the provision stated, ''except for interim claims submitted for qualifying outlier cases, all claims reimbursed under the CHAMPUS DRG-based payment system are to be priced as of the date of admission, regardless of when the claim is submitted.'' While there may have been a need to reference interim claims when the August 1988 Final rule was written and as we transition from ''billed'' charges to the DRG-based payment method, that is no longer the case. Consequently, the interim claims reference has been deleted.

B. Updating the Pricing Approach

In the early stages of the DRG-based payment system, the approach of pricing claims based on the date of the beneficiary's admission to the hospital was an effective operational policy for TRICARE. At the time TRICARE adopted the DRG-based payment system, it was the first prospective payment system of its kind. TRICARE decided to use the date of admission to price claims, allowing hospitals to be reimbursed for inpatient services under the same payment methodology they expected to be used when the patient was admitted. However, this is no longer the industry standard. Consequently, in order to be consistent with industry standards utilized by Medicare and other payers, TRICARE policy shall require all final claims to be priced based on the rates and weights that are in effect on a beneficiary's date of discharge.

While pricing using the date of discharge applies to all final claims, the change in approach will result in different pricing only for those relatively few claims that span fiscal years (FYs). That is, currently if an admission occurs on September 29 of a fiscal year (e.g., FY 2013) and the discharge occurs for example on October 2 of the subsequent fiscal year

(e.g., FY2014) the payment rate is based upon the DRG rates and weights in effect on September 29, 2013, or the prior fiscal year (FY2013), rather than on October 2, 2013, (FY2014). On and after this rule's applicability date, if an admission occurs for instance on September 29 of a fiscal year (e.g., FY2014) and the discharge occurs on October 1, 2014, or later (i.e., FY2015) the claim will be priced using the rates and weights in place on the date of discharge (e.g., FY2015). Please note that the rates and weights for the DRG-based payment system are updated every fiscal year and are based on the previous fiscal year's TRICARE claims data. As a result, the applicability date of October 1, 2014, is established to coincide with the next annual payment system update.

To improve consistency with other payers for health care services and reduce any administrative burden on providers, we are therefore changing our regulations to provide that all claims reimbursed on the DRG-based payment system will be priced as of the date of discharge starting with discharges dated October 1, 2014, or later.

IV. Public Comments

The proposed rule was published in the **Federal Register** (78 FR 10579–10581) on February 14, 2013, for a 60-day public comment period. We received one comment from one respondent.

Comment: Billing and adjustments for a hospital stay are completed on the last day.

Response: We interpret the commenter's statement as acknowledging that billing and adjustments for a patient's hospital stay are typically performed after the patient has been discharged. Consequently pricing an inpatient stay according to the weights and rates on the date of discharge is appropriate and desirable. We agree with the commenter's statement. Beginning with discharges that occur on or after October 1, 2014, the pricing of TRICARE inpatient claims reimbursed under the DRG methodology will be based on the weights and rates that are in effect on the date of discharge.

We will monitor discharge patterns and lengths of stay following this revision and may take additional regulatory action if we observe any unintended adverse consequences due to calculating payments for claims based on the rates and weights on the date of discharge as opposed to admission.

V. Regulatory Procedures

A. Overall Impact

DoD has examined the impacts of this Final rule as required by Executive Orders (E.O.s) 12866 (September 1993, Regulatory Planning and Review) and 13563 (January 18, 2011, Improving Regulation and Regulatory Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Congressional Review Act (5 U.S.C. 804(2)).

1. Executive Order 12866 and Executive Order 13563

Section 801 of title 5, United States Code, and Executive Order (E.O.) 12866 require certain regulatory assessments and procedures for any major rule or significant regulatory action, defined as one that would result in an annual effect of $100 million or more on the national economy or which would have other substantial impacts. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. It has been certified that this rule is not economically significant, and has been reviewed by the Office of Management and Budget as required under the provisions of E.O. 12866 and E.O. 13563.

2. Congressional Review Act. 5 U.S.C. 801

Under the Congressional Review Act, a major rule may not take effect until at least 60 days after submission to Congress of a report regarding the rule. A major rule is one that would have an annual effect on the economy of $100 million or more or have certain other impacts. This Final rule is not a major rule under the Congressional Review Act.

3. 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 Final 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 Final rule is not subject to the requirements of the RFA.

4. 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 in any one year. It has been certified 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, and thus this Final rule is not subject to this requirement.

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

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

6. 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 Final rule does not have federalism implications, as set forth in E.O. 13132.

List of Subjects in 32 CFR Part 199

Claims, Dental health, 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 199.14 is amended by revising paragraph (a)(1)(i)(C)(*3*) to read as follows:

§ 199.14 Provider reimbursement methods.

(a) * * *
(1) * * *
(i) * * *
(C) * * *

(*3*) *Pricing of claims.* All final claims with discharge dates of September 30,

2014, or earlier that are reimbursed under the CHAMPUS DRG-based payment system are to be priced as of the date of admission, regardless of when the claim is submitted. All final claims with discharge dates of October 1, 2014, or later that are reimbursed under the CHAMPUS DRG-based payment system are to be priced as of the date of discharge.

* * * * *

Dated: May 12, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–11194 Filed 5–20–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2014–0250]

RIN 1625–AA08

Special Local Regulation; Jones Beach Air Show; Atlantic Ocean, Sloop Channel Through East Bay, and Zach's Bay; Wantagh, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation on the navigable waters of the Atlantic Ocean, Sloop Channel through East Bay and Zach's Bay near Jones Beach State Park in Wantagh, NY for the Jones Beach Air Show. This action is necessary to provide for the safety of life of event participants, spectators, and other waterway users during this event. The special local regulation will facilitate public notification of the event and provide protective measures for the maritime public and event participants from the hazards associated with the Jones Beach Air Show. Entering into, transiting through, remaining, or anchoring within these regulated areas would be prohibited unless authorized by the captain of the Port (COTP) Sector Long Island Sound.

DATES: This rule is effective from May 23, 2014 to May 25, 2014.

This rule will be enforced from 9 a.m. to 3:30 p.m. on May 23, 2014, and from 9 a.m. to 9 p.m. beginning May 24, 2014 through May 25, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2014–0250]. To view documents mentioned in this preamble as being available in the docket, go to *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 rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Scott Baumgartner, Prevention Department, Coast Guard Sector Long Island Sound, (203) 468–4559, *Scott.A.Baumgartner@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

On May 24, 2013, the Coast Guard published a Final Rule, entitled, ''Safety Zones and Special Local Regulations; Recurring Marine Events in Captain of the Port Long Island Sound Zone'' in the **Federal Register** (78 FR 31402). This rulemaking established multiple safety zones and special local regulations throughout the Captain of the Port Sector Long Island Sound Zone including a safety zone for the Jones Beach Air Show. This final rule was preceded by a NPRM entitled, ''Safety Zones and Special Local Regulations; Recurring Marine Events in Captain of the Port Long Island Sound Zone'' that was published in the **Federal Register** (78 FR 20277). No public comments were received for this proposed rulemaking. There were no requests received for a public meeting and none were held.

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because an NPRM would be impracticable. Since the Jones Beach Air Show is scheduled to take place over three days beginning May 23, 2014 through May 25, 2014, it is impracticable to draft, publish, and receive public comment on this rulemaking via an NPRM and still publish a final rule before the event is scheduled to take place. Delaying this rulemaking by waiting for a comment period to run would also reduce the Coast Guard's ability to promote the safety of event participants and the maritime public during this event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** for the same reasons stated above.

B. Basis and Purpose

The legal basis for this temporary rule is 33 U.S.C. 1233 and Department of Homeland Security Delegation No. 0170.1 which collectively authorize the Coast Guard to define regulatory special local regulations.

The Jones Beach Air Show will take place from May 23, 2014 through May 25, 2014. The first day of the event, May 23, 2014 the Jones Beach Air Show will not be open to the general public but aircraft involved in the event will be conducting practice runs over the Atlantic Ocean. On Saturday, May 24, 2014 and Sunday, May 25, 2014 the Air Show will be open and operating from 10 a.m. through 3 p.m. The event will involve numerous aircraft performing various aerial maneuvers. These aircraft and associated event participants will be operating at high speeds and/or in close proximity to other event participants and spectators. These aerial activities present multiple hazards, including those associated with in-flight accidents that could result in collision, fire, and debris fall-out. The Jones Beach Air show and these aerial activities attract thousands of spectators to Jones Beach State Park as well as a significant number of spectator vessels to the waters around Jones Beach State Park. The operation of these numerous spectator vessels in such close proximity to each other presents additional hazards to the maritime public beyond those associated with the aerial activities.

During a review of the regulations currently published for the Jones Beach Air Show in Table 1 of 33 CFR 165.151 the Coast Guard discovered that the positions marking the corners of the area regulated as a safety zone were published out of order and when