§ 50.3 Definitions.

* * * * *

(n) *Assent* means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object should not, absent affirmative agreement, be construed as assent.

* * * * *

(r) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation.

(s) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

■ 3. Revise § 50.51 to read as follows:

§ 50.51 Clinical investigations not involving greater than minimal risk.

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which no greater than minimal risk to children is presented may involve children as subjects only if the IRB finds that:

(a) No greater than minimal risk to children is presented; and

(b) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in § 50.55.

■ 4. Revise the introductory text of § 50.52 to read as follows:

§ 50.52 Clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects.

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, may involve children as subjects only if the IRB finds that:

* * * * *

■ 5. Revise the introductory text of § 50.53 to read as follows:

§ 50.53 Clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.

Any clinical investigation within the scope described in §§ 50.1 and 56.101 of this chapter in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, may involve children as subjects only if the IRB finds that:

* * * * *

■ 6. Revise paragraph (a) of § 50.54 to read as follows:

§ 50.54 Clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

* * * * *

(a) The IRB finds that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

* * * * *

■ 7. Revise paragraph (e) of § 50.55 to read as follows:

§ 50.55 Requirements for permission by parents or guardians and for assent by children.

* * * * *

(e) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine, in accordance with and to the extent that consent is required under part 50, that the permission of each child's parents or guardian is granted.

(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for clinical investigations to be conducted under § 50.51 or § 50.52.

(2) Where clinical investigations are covered by § 50.53 or § 50.54 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

* * * * *

PART 56—INSTITUTIONAL REVIEW BOARDS

■ 8. The authority citation for 21 CFR part 56 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 9. Revise in § 56.109 the second sentence of paragraph (h) to read as follows:

§ 56.109 IRB review of research.

* * * * *

(h) * * * When some or all of the subjects in a study that was ongoing on April 30, 2001, are children, an IRB must conduct a review of the research to determine compliance with part 50, subpart D of this chapter, either at the time of continuing review or, at the discretion of the IRB, at an earlier date.

Dated: February 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04387 Filed 2–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2011–HA–0059]

RIN 0720–AB52

TRICARE; Elimination of the Non-Availability Statement (NAS) Requirement for Non-Emergency Inpatient Mental Health Care

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule eliminates the requirement that states a NAS is needed for non-emergency inpatient mental health care in order for a TRICARE Standard beneficiary's claim to be paid. Currently, NAS are required for non-emergency inpatient mental health care for TRICARE Standard beneficiaries who live within a military treatment facility catchment area. At this time, the number of NASs issued is negligible as most mental health admissions are emergency admissions. Requiring a NAS for a relatively few non-emergency inpatient mental health admissions is disproportionate to the cost of maintaining the systems necessary to process and coordinate the NAS.

DATES: Effective March 28, 2013.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Hart, TRICARE Policy and Operations, TRICARE Management Activity, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041, 703–681–0047.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of This Regulatory Action

a. Currently, NAS are required for non-emergency inpatient mental health care for TRICARE Standard beneficiaries who live within a military treatment facility catchment area. Pursuant to section 1080(c)(2) of title 10, United States Code, the Secretary can waive the requirement to obtain NASs following an evaluation of the effectiveness of such statements in optimizing the use of

facilities of the uniformed services. At this time, the number of NASs issued is negligible as most mental health admissions are emergency admissions. Requiring a NAS for a relatively few non-emergency inpatient mental health admissions is disproportionate to the cost of maintaining the systems necessary to process and coordinate the NAS. This final rule eliminates the requirement for a NAS for non-emergency inpatient mental health care in order for the TRICARE Standard beneficiary's claim to be paid.

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

II. Summary of the Major Provisions of This Regulatory Action

This final rule eliminates the requirement for a NAS for non-emergency inpatient mental health care in order for the TRICARE Standard beneficiary's claim to be paid.

The elimination of the requirement for a NAS for non-emergency inpatient mental health care for TRICARE Standard beneficiaries is separate and distinct from the ongoing right of first refusal for specialty services requested by a civilian provider under TRICARE Prime, if the services are available at the MTF, or the ongoing statutory requirement for preadmission authorization before inpatient mental health services may be provided. This final rule does not eliminate the right of first refusal or requirement for preadmission authorization.

In reviewing the proposed rule, we discovered that we had inadvertently deleted not only the requirement to obtain a NAS for non-emergency inpatient mental health services for TRICARE Standard beneficiaries living within the 40-mile catchment area of a military treatment facility, but also the Department's general implementation of section 721 of Public Law 106–398, as amended by section 735 of Public Law 107–107, regarding the Secretary's statutory authority to require a NAS. We have remedied that oversight in this final rule, thereby preserving the option to impose the requirement to obtain NASs in the future, consistent with existing statutory authority, should circumstances change and a demonstration be made that, by performing specific procedures at affected military medical treatment facilities, use of such facilities would be optimized and significant costs avoided. Section 199.4(a)(9) is thereby amended to retain this general authority while still eliminating the current requirement to obtain a NAS for non-emergency inpatient mental health services.

III. Costs and Benefits of This Regulatory Action

There are no anticipated budgetary health care cost increases. Requiring a NAS for a relatively few non-emergency inpatient mental health admissions is disproportionate to the cost of maintaining the systems necessary to process and coordinate the NAS.

Public Comments

The proposed rule was published in the **Federal Register** on September 16, 2011 (76 FR 57690). No public comments were received.

Regulatory Procedures

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

Executive Order 12866 requires that a comprehensive regulatory impact analysis be performed on any economically 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. This final rule is not economically significant nor a significant regulatory action as defined under these executives orders.

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

This rule does not contain unfunded mandates. It 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 1 year.

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

The Regulatory Flexibility Act (RFA) requires that each Federal Agency prepare, and make available for public comment, 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 will not have a significant impact on a substantial number of small entities for purposes of the RFA. Thus this final rule is not subject to this requirement.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3511)

This final rule will not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, ''Federalism''

We have examined the impacts of the rule under Executive Order 13132 and it does not have policies that have 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, therefore, consultation with State and local officials is not required.

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 199.4 is amended by revising paragraph (a)(9) to read as follows:

§ 199.4 Basic program benefits.

* * * * *

(a) * * *

(9) *Nonavailability Statements within a 40-mile catchment area.* Unless required by action of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) under this paragraph (a)(9), nonavailability statements are not required. If they are required by ASD(HA) action, in some geographic locations, CHAMPUS beneficiaries not enrolled in TRICARE Prime may be required to obtain a nonavailability statement from a military medical treatment facility in order to receive specifically identified health care services from a civilian provider. If the required care cannot be provided through the Uniformed Service facility, the hospital commander, or a designee, will issue a Nonavailability Statement (NAS) (DD Form 1251). Failure to secure such a statement may waive the beneficiary's rights to benefits under CHAMPUS/TRICARE.

(i) With the exception of maternity services, the ASD(HA) may require an NAS prior to TRICARE cost-sharing for additional services from civilian sources if such services are to be provided to a beneficiary who lives within a 40-mile catchment area of an MTF where such services are available and the ASD(HA):

(A) Demonstrates that significant costs would be avoided by performing specific procedures at the affected MTF or MTFs; or

(B) Determines that a specific procedure must be provided at the

affected MTF or MTFs to ensure the proficiency levels of the practitioners at the MTF or MTFs; or

(C) Determines that the lack of NAS data would significantly interfere with TRICARE contract administration; and

(D) Provides notification of the ASD(HA)'s intent to require an NAS under this authority to covered beneficiaries who receive care at the MTF or MTFs that will be affected by the decision to require an NAS under this authority; and

(E) Provides at least 60-day notification to the Committees on Armed Services of the House of Representatives and the Senate of the ASD(HA)'s intent to require an NAS under this authority, the reason for the NAS requirement, and the date that an NAS will be required.

(ii) Rules in effect at the time civilian medical care is provided apply. The applicable rules and regulations regarding Nonavailability Statements in effect at the time the civilian care is rendered apply in determining whether a NAS is required.

(iii) The Director, TMA is responsible for issuing the procedural rules and regulations regarding Nonavailability Statements. Such rules and regulations should address:

(A) When and for what services a NAS is required. However, a NAS may not be required for services otherwise available at an MTF located within a 40-mile radius of the beneficiary's residence when another insurance plan or program provides the beneficiary's primary coverage for the services. This requirement for an NAS does not apply to beneficiaries enrolled in TRICARE Prime, even when those beneficiaries use the point-of-service option under § 199.17(n)(3) of this part; and

(B) When and how notifications will be made to a beneficiary who is not enrolled in TRICARE Prime as to whether or not he or she resides in a geographic area that requires obtaining a NAS; and

(C) What information relating to claims submissions, including the documentation, if any, that is required to document that a valid NAS was issued. However, when documentation of a NAS is required, then that documentation shall be valid for the adjudication of CHAMPUS claims for all related care otherwise authorized by this part which is received from a civilian source while the beneficiary resided within the Uniformed Service facility catchment area which issued the NAS.

(iv) In the case of any service subject to a NAS requirement under this paragraph (a)(9) and also subject to a preadmission (or other pre-service) authorization requirement under § 199.4 or § 199.15 of this part, the administrative processes for the NAS and pre-service authorization may be combined.

* * * * *

Dated: February 1, 2013.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–03418 Filed 2–25–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[Docket ID: DOD–2011–HA–0035]

RIN 0720–AB49

TRICARE; TRICARE Sanction Authority for Third-Party Billing Agents

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule will provide the Director, TRICARE Management Activity (TMA), or designee, with the authority to sanction third-party billing agents by invoking the administrative remedy of exclusion or suspension from the TRICARE program. Such sanctions may be invoked in situations involving fraud or abuse on the part of third-party billing agents that prepare or submit claims presented to TRICARE for payment.

DATES: *Effective date:* This rule is effective March 28, 2013.

FOR FURTHER INFORMATION CONTACT: Ms. Ann N. Fazzini, Medical Benefits and Reimbursement Branch, TMA, telephone, (303) 676–3803.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Overview

A. Purpose of the Regulatory Action

As stated in the proposed rule, TRICARE has regulatory authority under 32 Code of Federal Regulations (CFR) 199.9 to invoke sanctions in situations involving fraud or abuse on the part of providers of TRICARE services. A provider is defined in 32 CFR 199.2 as, ''A hospital or other institutional provider, a physician, or other individual professional provider, or other provider of services or supplies as specified in § 199.6 of this part.'' Third-party billing agents do not meet the definition of a provider as stated in 32 CFR 199.2, nor do TRICARE regulations currently define third-party billing agents.

Title 42 of the CFR subpart C—Exclusions at 42 CFR 402.200(b)(1) provides for the imposition of an exclusion from the Medicare and Medicaid programs (and, where applicable, other Federal health care programs) against persons that violate the provisions provided in § 402.1(e) (and further described in § 402.1(c)). However, TRICARE had no independent regulatory authority to sanction or exclude third-party billing agents. This final rule provides that authority.

B. Summary of Major Provisions

This final rule establishes that such entities, when acting on behalf of a provider, are held to an equal standard in regard to accuracy and honesty when filing claims for services and supplies under the TRICARE program. As such, these entities should be subject to the same administrative controls applied to providers in ensuring that funds are disbursed appropriately. This rule will allow TRICARE to sanction third-party billing agents to prevent the payment of false or improper billings.

C. Summary of Costs and Benefits

By expanding the scope of sanctioning authority to include third-party billing agents, TRICARE costs are not anticipated to increase in this area. Rather, by expanding the sanctioning authority to include third-party billing agents in situations of fraud or abuse, the program is safeguarding benefit dollars from being expended for fraudulent or abusive charges. The anticipated result of this final rule is a savings benefit to the program.

II. Department of Defense Inspector General Report on TRICARE Controls Over Claims Prepared by Third-Party Billing Agents

The Department of Defense, Office of Inspector General (DoD IG) initiated an audit in February 2008 to review TRICARE controls over claims submitted by third-party billing agents (Department of Defense Inspector General Report No. D–2009–037—''TRICARE Controls Over Claims Prepared by Third-Party Billing Agencies''). The DoD IG published a report on December 31, 2008. The report included a recommendation that the Director, TMA strengthen internal controls by initiating action to obtain statutory or regulatory authority to sanction billing agencies or any entities that prepare or submit improper health care claims to TRICARE contractors.