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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Parts 199 and 200

[DOD–2018–HA–0059]

RIN 0720–AB74

Civil Money Penalties and Assessments Under the Military Health Care Fraud and Abuse Prevention Program

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement authority provided to the Secretary of Defense under the Social Security Act. This authority allows the Secretary of Defense as the administrator of a Federal healthcare program to impose civil monetary penalties (CMPs or penalties) as described in section 1128A of the Social Security Act against providers and suppliers who commit fraud and abuse in the TRICARE program. This proposed rule establishes a program within the DoD to impose civil monetary penalties for certain such unlawful conduct in the TRICARE program. To the extent applicable, we are proposing to adopt the Department of Health and Human Service’s (HHS’s), well-established CMP rules and procedures. This will enable both TRICARE and TRICARE providers to rely upon Medicare precedents and guidance issued by the HHS Office of Inspector General regarding conduct that implicates the civil monetary penalty law. The

program to impose civil monetary penalties in the TRICARE program shall be called the Military Health Care Fraud and Abuse Prevention Program.

DATES: To ensure consideration, comments must be received no later than [INSERT 60 DAYS FROM THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Defense Health Agency may not fully consider comments received after this date.

ADDRESSES: You may submit comments identified by docket number and/or RIN number and title, by any of the following methods:

Federal eRulemaking 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, 4800 Mark Center Drive, Suite 08D09, Attn: Mailbox 24, Alexandria, VA 22350-1700.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (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: Michael J. Zleit, at 703-681-6012.

SUPPLEMENTARY INFORMATION:

I. EXECUTIVE SUMMARY

1. Purpose.

A. *Need For Regulatory Action*

The Defense Health Agency (DHA), the agency of the Department of Defense responsible for administration of the TRICARE Program, has as its primary mission the support and delivery of an integrated, affordable, and high quality health service to all DoD beneficiaries and in doing so, is a responsible steward of taxpayer dollars. In recent years, fraud and abuse has been inhibiting DHA's mission. One example involves compound drugs. In fiscal year 2004, DoD paid about \$5 million for compound drugs. Ten years later in fiscal year 2014, the amount paid had risen over 10,000% exceeding \$514 million, and for fiscal year 2015, the cost exceeded \$1.3 billion in expenditures just for compound drugs. Significantly, compounded drugs make up only 0.5 percent of the total number of prescriptions provided through TRICARE, but in 2015 accounted for more than 20 percent of TRICARE's total pharmacy expenditures. The astronomical increase in expenditures related to compound drugs was almost solely due to fraud and abuse, resulting in many investigations and prosecutions by the Department of Justice (DOJ). However, because DOJ is responsible for the prosecution of all fraud and abuse in all Federal healthcare programs, including Medicare, TRICARE, and the Federal Employees Health Benefits Program and does not have unlimited resources, DOJ must prioritize cases and is unable to prosecute a large portion of those entities who commit fraud and abuse in the TRICARE Program. Therefore, the Department of Defense, acting through the DHA, seeks to implement its authority under section 1128A(m) of the Social Security Act (42 U.S.C. 1320a-7a(m)) to initiate administrative proceedings to impose civil monetary penalties against those who commit fraud and abuse in the TRICARE Program. Because CMPs may be imposed in addition to criminal proceedings, we believe that the establishment of a CMP Program within the DoD will serve a complementary function to the criminal justice process and provide additional deterrence to fraudulent actions against the Federal TRICARE Program and the recovery of funds lost to

fraud and abuse. The purpose of this proposed rule utilizing CMP authority is to ensure the integrity of TRICARE and make the government whole for funds lost to fraud and abuse, which is necessary to the delivery of an integrated, affordable, and high quality health service for all DoD beneficiaries.

B. Costs and Benefits of This Proposed Rule

This proposed rule would reduce Defense Health Program requirements by \$74 million from FY 2020 - FY 2024. The savings estimates were based on recent history of TRICARE fraud and abuse audits and investigations that, for a variety of reasons, did not result in criminal or civil actions by the Department of Justice under other legal authorities. The saving estimates were based on the estimate of 50 cases per year with an average penalty of \$600,000 per case and a collection rate of 60%. Additionally, the estimated recovery amount subtracts out appeal costs, full-time equivalent costs, and administrative costs.

The proposed rule along with additional proposed legislation allows the funds collected to be credited to appropriations available for expenses of the affected DoD health care program. Based on the results of the HHS civil money penalty program, the expectation is that funds recovered will more than pay for the activities associated with investigating abuses and administering the civil money penalty program, producing savings for DoD.

Because CMPs may be imposed in addition to criminal proceedings, we believe that the benefit of the establishment of a CMP Program within the DoD will serve a complementary function to the criminal justice process and provide additional deterrence to fraudulent actions against the Federal TRICARE Program and the recovery of funds lost to fraud and abuse. We believe the recovery of funds lost to fraud and abuse will make the government whole and will

help ensure the continued delivery of an integrated, affordable, and high quality health service for all DoD beneficiaries.

C. Authority Provided to all Federal Healthcare Programs

The specific legal authority authorizing the Department of Defense, to establish a program to impose CMPs in the TRICARE Program is provided in section 1128A(m) of the Social Security Act [42 U.S.C. 1320a-7a(m)]. This provision of law authorizes Federal Departments other than HHS with jurisdiction over a Federal health care program (as defined in section 1128B(f) of the Social Security Act), to impose CMPs as enumerated in section 1128A of the Social Security Act. Some of the CMPs enumerated in section 1128A of the Social Security Act limit the applicability to conduct only involving Medicare and Medicaid; therefore, this proposed rule would implement all CMP authorities under section 1128A that are not specifically limited to Medicare, Medicaid, or other HHS-exclusive authority.

D. Summary of the major provisions of the proposed rule.

We propose to establish Civil Monetary Penalties (CMP) regulations at 32 CFR part 200 to implement authority provided to the Department of Defense under section 1128A of the Social Security Act, as amended. The proposed rule closely follows the organization and substance of HHS's CMP regulations. We propose to follow HHS's process and procedure for imposing CMPs, as well as HHS's methodology for calculating the amount of penalties and assessments. Additionally, for ease of interpretation and transparency, we have adopted HHS's numerical structure for this proposed regulation. Accordingly, the numerical provisions of the proposed 32 CFR part 200 directly correspond to HHS's numerical provisions at 42 CFR part 1003. Following this organizational construct and HHS rules and procedures, the proposed rule addresses such matters as: liability for penalties and assessments, determinations regarding the

amount of penalties and assessments, CMPs and assessments for false and fraudulent claims and other similar misconduct, penalties and assessments for unlawful kickbacks, CMPs and assessments for contracting organization misconduct, procedures for the imposition of CMPs and assessments, judicial review, time limitations for CMPs and assessments, statistical sampling, and appeals.

II. PROVISIONS OF THE PROPOSED RULE

A. BACKGROUND

For over 25 years, the HHS Office of Inspector General (OIG) has exercised the authority to impose CMPs, assessments, and exclusions in furtherance of its mission to protect the Federal health care programs and their beneficiaries from fraud and abuse. As those programs have changed over the last two decades, HHS-OIG has received new fraud-fighting CMP authorities in response. Section 231 of HIPAA expanded the reach of CMPs to include federal health programs other than those funded by HHS. In 1977, Congress first mandated the exclusion of physicians and other practitioners convicted of program-related crimes from participation in Medicare and Medicaid through the Medicare-Medicaid Anti-Fraud and Abuse Amendments, Public Law 95-142 (now codified at section 1128 of the Social Security Act (the SSA)). This was followed in 1981 with Congress enacting the Civil Monetary Penalties Law (CMPL), Public Law 97-35, section 1128A of the SSA, 42 U.S.C. 1320a-7a, to further address health care fraud and abuse. The CMPL authorized the Secretary to impose penalties and assessments on a person, as defined in 42 CFR part 1003, who defrauded Medicare or Medicaid or engaged in certain other wrongful conduct. The CMPL also authorized the Secretary of Health and Human Services to exclude persons from Medicare and all State health care programs

(including Medicaid). Congress later expanded the CMPL and the scope of exclusion to apply to all Federal health care programs. The Secretary of HHS delegated the CMPL's authorities to HHS-OIG. 53 FR 12993 (April 20, 1988). Since 1981, Congress has created various other CMP authorities covering numerous types of fraud and abuse. These new authorities were also delegated by the Secretary to HHS-OIG and were added to part 1003.

In 1996, Section 231 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) expanded the reach of certain CMPs to include Federal health programs other than HHS, including specific CMPs that may be implemented to prevent fraud and abuse against programs such as TRICARE. The CMPL authorizes the Department or agency head to impose CMPs, assessments, and program exclusions against individuals and entities who submit false or fraudulent, or otherwise improper claims for payment under Federal healthcare programs administered by that Department of agency. HHS has an active, robust process in place to seek CMPs. Additionally, in September 2016, HHS substantially increased the amount of the penalty it may collect for each act of fraud and abuse. The Office of Personnel Management (OPM) also actively seeks civil monetary penalties under the Federal Employees Health Benefits (FEHB) Program. Subsequent to HIPAA, Congress expanded CMP authorities to reach additional conduct, such as: (1) failure to grant an OIG timely access to records, upon reasonable request; (2) ordering or prescribing while excluded when the excluded person knows or should know that the item or service may be paid for by a Federal health care program; (3) making false statements, omissions, or misrepresentations in an enrollment or similar bid or application to participate in a Federal health care program; (4) failure to report and return an overpayment that is known to the person; and (5) making or using a false record or statement that is material to a

false or fraudulent claim. Most recently, in the Bipartisan Budget Act of 2018, Congress doubled the maximum amount of penalties and assessments under section 1128A.

B. IMPOSITION OF CMPs and ASSESSMENTS IN THE TRICARE PROGRAM

1. Introduction

As noted above, section 1128A(m) of the SSA authorizes the applicable Department head to impose civil monetary penalties (CMPs), assessments, and program exclusions against individuals and entities who submit false or fraudulent, or otherwise improper claims for payment. To date, DoD has not implemented its authority under this law, but proposes to now do so. The Defense Health Agency will utilize this authority and create the regulatory framework in this proposed rule to initiate a program to impose civil monetary penalties against those who commit fraud or abuse against the TRICARE program. The DHA will utilize the authority in section 1128A of the SSA to impose civil monetary penalties and assessments, but, unlike the HHS CMP Program, TRICARE will not utilize authority to impose program exclusions as part of its CMP program. Rather, program exclusions in the TRICARE program will remain under TRICARE's established authority and process at 32 CFR 199.9(f). In order to integrate this proposed rule into TRICARE's exclusion process under 32 CFR 199.9(f), we propose to amend 32 CFR 199.9(f)(1)(ii) by adding a sentence at the end of the provision stating: "A final determination of an imposition of a civil monetary penalty under 32 CFR part 200 shall constitute an administrative determination of fraud and abuse." We believe that this amendment will clarify that a final determination of an imposition of a CMP, implicating conduct under 32 CFR part 200, may subject the respondent of

the CMP to exclusion as authorized under 32 CFR 199.9(f)(1)(ii).

2. Delegation of Authority

Section 1128A(m) of the SSA provides the Secretary of Defense with CMP authority over claims involving the TRICARE Program. This proposed rule reflects a delegation of authority from the Secretary of Defense to the DHA Director to impose CMPs and assessments against any person who has violated one or more provisions of CMPL as applicable to the TRICARE Program. We propose that the authority at 32 CFR 200.150 will include all powers to impose and compromise civil monetary penalties and assessments under section 1128A of the Social Security Act.

3. Prohibited Acts

We propose that the following prohibited acts under section 1128A(a) [42 U.S.C. 1320a-7a(a)] be subject to the imposition of civil monetary penalties in the TRICARE Program. These prohibitions include (but are not limited to) any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5) of this section) that—

- knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency a claim that—
 - Is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a

greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided [1320a-7a(a)(1)(A)];

- Is for a medical or other item or service and the person knows or should know the claim is false or fraudulent [1320a-7a(a)(1)(B)];
 - Is presented for a physician service by a person who knows or should know that the individual who furnished the service— (i) was not licensed as a physician, (ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing), or (iii) represented to the patient at the time the service was furnished that the physician was certified in a medical specialty by a medical specialty board when the individual was not so certified [1320a-7a(a)(1)(C)];
 - Is for a medical or other item or service furnished during a period in which the person was excluded from the TRICARE program under 32 CFR 199.9(f) or other Federal health care program (as defined in section 1128B(f) of the Social Security Act) under which the claim was made pursuant to Federal law [1320a-7a(a)(1)(D)];
 - Is for a pattern of medical or other items or services that the person knows or should know are not medically necessary [1320a-7a(a)(1)(E)].
- arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1320a-7b(f) of this title), for the provision of items or services for which payment may be made under such a program; [1320a-7a(a)(6)].

- commits an act described in paragraph (1) or (2) of section 1320a–7b(b) of title 42; [1320a-7a(a)(7)].
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; [1320a-7a(a)(8)].
- fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Office of Inspector General (OIG), for the purpose of audits, investigations, evaluations, or other statutory functions of the OIG; [1320a-7a(a)(9)].
- orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so defined), in the case where the person knows or should know that a claim for such medical or other item or service will be made under such a program [1320a-7a(a)(8)]; (Note: there are two section 1320a-7a(a)(8) provisions enacted into the statute).
- knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined) [1320a-7a(a)(9)]; (Note: there are two section 1320a-7a(a)(9) provisions enacted into the statute).
- knows of an overpayment (as defined in paragraph (4) of section 1128J(d) [42 U.S.C. 1320a-7k(d)]) and does not report and return the overpayment in accordance with such section [1320a-7a(a)(10)].

4. Coordination with HHS and DOJ.

DHA will coordinate with the Department of Justice (DOJ) and Defense Criminal Investigative Organizations (DCIOs) in resolving all CMP matters.

Allegations of fraud will be referred promptly for investigation to the appropriate DCIO consistent with the requirements of Department of Defense Instruction 5505.02. In cases where DOJ or the appropriate DCIO does not participate the case will be governed by either DHA's or HHS's CMPL authorities depending on whether the relevant claims are primarily TRICARE Claims or Medicare Claims. In cases involving mixed Medicare and TRICARE Claims, DHA will seek to resolve only those cases which consist of primarily TRICARE claims. Medicare will take the lead role in resolving cases which consist of primarily Medicare claims. Administrators from both HHS and the DHA will coordinate in resolving cases with mixed TRICARE and Medicare claims. If claims implicated by CMPL are primarily TRICARE claims, those claims will be governed by DHA's applicable CMP authorities. In some cases, disclosing parties may request release under the False Claims Act (FCA), and in other cases, DOJ may choose to participate in the disposition of the matters. DOJ determines the approach in cases in which it is involved. If DOJ participates, the matter will be resolved as DOJ determines is appropriate consistent with its resolution of FCA cases.

5. Amount of Penalties and Assessments.

In order to ensure full compliance with the authority delegated to the Secretary of Defense in section 1128A(m), DoD proposes to impose penalties and assessments in the amount not to exceed the maximum adjusted civil penalty amounts prescribed in 32 CFR part 269. DoD proposes to follow annually updated penalty amounts, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal

Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74); and the Bipartisan Budget Act of 2018.

6. Exclusion.

The time period and effect of exclusion will follow TRICARE's established exclusion process at 32 CFR 199.9(f). A person who has been excluded from the TRICARE Program may apply for reinstatement at the end of the period of exclusion. The process for reinstatement will be in accordance with the pertinent provisions of 32 CFR 199.9(h). Unlike HHS's CMP process, whereby HHS imposes penalties, assessments and exclusions, DHA will not exercise authority over exclusions in the TRICARE Program as part of the CMP implementation. Exclusion actions under the TRICARE Program will continue to be governed under the established process at 32 CFR 199.9(f). Appeals of exclusions will be in accordance with the established process at 32 CFR 199.10 and will not be part of the proposed CMP appeals process.

Additionally, as part of this proposed rule we are proposing an amendment to 32 CFR 199.9(f)(1)(ii) that would clarify that a final determination of an imposition of a civil monetary penalty under 32 CFR part 200 would be considered an administrative determination of fraud and abuse. By clarifying that a final determination of an imposition of a civil monetary penalty is an administrative determination of fraud and abuse, it will allow the TRICARE program an additional, appropriate basis for exclusion under the existing exclusion process at §199.9(f). Therefore, once a final determination has been made to impose a CMP, the claim will be referred for consideration of exclusion pursuant to 32 CFR 199.9(f), under

the normal TRICARE process where there has been a determination of fraud and abuse.

7. Notice of a Proposed Determination.

Where sufficient evidence supports the imposition of a CMP, the DHA may serve a notice of proposed determination on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure detailing the basis and remedy sought. This proposed rule at 32 CFR 200.1500 mirrors the requirements of 42 CFR 1003.1500, but eliminates the requirement in 42 CFR 1003.1500(a)(7) involving a termination of a Medicare Provider Agreement pursuant to 1866(b)(2)(C) of the SSA, because the provision governing Medicare Provider Agreements is not applicable to the TRICARE Program.

8. Factors Relevant to Determining Amount of Penalty and Assessment.

For clarity, to improve transparency in DHA's decision-making processes, and for consistency with HHS's CMP process, we propose to use the very same factors in determining the amount of penalties and assessments for violations as HHS uses codified at 42 CFR 1003.140. As codified in the proposed regulation at 32 CFR 200.140, the primary factors for determining the amount of penalties and assessments for violations that we will consider are: (1) the nature and circumstances of the violation, (2) the degree of culpability of the person, (3) the history of prior offenses, (4) other wrongful conduct, and (5) other matters as justice may require.

9. Statute of Limitations.

In accordance with the authority delegated to the Secretary of Defense, the

imposition of CMPs in the TRICARE Program will be subject to a six year statute of limitations.

10. Statistical sampling and extrapolation.

The proposed regulation at §200.1580 provides that a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment. The use of statistical sampling will allow DHA to impose penalties and assessments based upon an extrapolated number and amount of claims. Additionally, statistical sampling will allow DHA to recover the extrapolated amount of overpaid funds through administrative recoupment.

11. Appeals of Civil Money Penalties and Assessments.

Administrative review of the imposition of a civil monetary penalty under the TRICARE Program will be before an Administrative Law Judge (ALJ). We propose entering into an arrangement with the HHS Departmental Appeals Board (DAB), pursuant to an interagency agreement between DoD and HHS for the DAB to hear TRICARE CMP appeals. However, as an alternative, DHA continues to evaluate possibly utilizing ALJ's currently assigned to the Department of Defense, and invites public comments on this alternative as well as the DAB proposal included in the text of the proposed rule.

The proposed appeals process would involve appeals of civil monetary penalties and assessments but not include appeals of exclusions, which will be governed by the established process at 32 CFR 199.9(f). We believe that DAB ALJs, would be good candidates to preside over TRICARE CMP appeals. DAB ALJs currently hear CMP appeals for the Medicare Program pursuant to HHS regulations at 42 CFR part 1005, which provide for a direct appeal to

the DAB for CMPs assessed by Medicare. During the appeals process, the DHA will have exclusive authority to settle any issues or case without consent of the ALJ. If the imposition of the CMP is successful on appeal, the determination of the CMP by the Secretary of Defense will become final. Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of DHA. A penalty or an assessment imposed under this program may be compromised by the DHA and may be recovered in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

Although we continue to evaluate the use of DoD ALJs, we believe that utilization of DAB ALJs and HHS's long established appeals process will be the most efficient means to adjudicate appeals under the TRICARE Program. The HHS appeals process would not add any additional process or burden to those in the industry who might be impacted by CMP law, because those entities implicated by the CMP law under TRICARE are for the most part the same entities that are already subject to the same civil monetary penalties law under Medicare. Additionally, we believe the adoption of HHS appeals regulations will assist the seamless adjudication of TRICARE Appeals by HHS ALJs with familiarity and experience working with the Medicare Appeals regulations.

We are proposing the adoption of a 120 day deadline, extending the 60 day deadline established in 42 CFR 1005.20(c) for the ALJ to issue a decision following the close of the record. We are also proposing extending the 60 day deadline established in 42 CFR 1005.21(i) for the Board to issue a decision following the close of the record. After consultation with the HHS DAB, the DAB has requested that in order to ensure adequate resources necessary to properly adjudicate CMP Appeals, including complex statistical sampling cases, that the

deadline to issue a decision be extended from 60 days to 120 days for the ALJ and the Board to issue a decision following the close of the record. We believe that the requested extension to 120 days for the issuance of an ALJ and Board decision provides appellants with appropriate due process. Accordingly, pursuant to the DAB recommendation we propose the deadline for decision by the ALJ in 42 CFR 1005.20(c) and the decision by the Board §1005.21(i) to be 120 days from the date the record is closed.

Therefore, with the exception of regulations involving exclusions and the extension of deadlines for the ALJ and Board to issue a decision, in part for purposes of uniformity with Medicare, we propose that the regulations at 42 CFR part 1005, §§ 1005.1 through 1005.23, be adopted in full to the extent applicable to appeals of civil monetary penalties and assessments in the TRICARE Civil Monetary Penalty Program. These appeals regulations are codified in this proposed regulation under 32 CFR 200.2001 through 200.2023.

III. REGULATORY IMPACT STATEMENT

Public Comments Invited

This is being issued as proposed rule to implement authority provided to the Secretary of Defense in section 1128A(m) of the SSA. DoD invites public comments on this proposed rule and is committed to considering all comments and issuing a final rule as soon as practicable.

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 in OMB Circular A-4 and Office of Information and Regulatory Affairs guidance on implementing E.O. 13771, this proposed rule does not involve

regulatory costs subject to E.O. 13771.

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Executive Orders 13563 and 12866 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, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rule is not a significant regulatory action. The 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; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in these Executive Orders.

This is not an economically significant rule because it does not reach that economic threshold of \$100 million or more. This proposed rule is designed to implement statutory provisions, authorizing the Department of Defense to impose CMPs. The vast majority of providers and Federal health care programs would be minimally impacted, if at all, by these proposed revisions. Accordingly, the aggregate economic effect of these regulations would be significantly less than \$100 million.

Congressional Review Act, 5 U.S.C. 804(2)

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 a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. This final rule is not a major rule, because it does not reach the economic threshold or have other impacts as required under the Congressional Review Act.

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

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most providers are considered small entities by having revenues of \$5 million to \$25 million or less in any one year. For purposes of the RFA, most physicians and suppliers are considered small entities. The aggregate effect of implementing a CMP Program within the TRICARE Program would be minimal. In summary, we have concluded that this proposed rule should not have a significant impact on the operations of a substantial number of small providers and that a regulatory flexibility analysis is not required for this rulemaking. Therefore, this proposed rule is not subject to the requirements of the RFA.

Public Law 104-4, Sec. 202, "Unfunded Mandates Reform Act"

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$140 million. As indicated above, these proposed rules implement statutory authority to impose CMPs on claims submitted to the TRICARE Program in a similar manner as implemented by the Department of Health and Human Services in the Medicare Program. It has been determined that there are no significant costs associated with the proposed implementation of a CMP Program to impose CMPs on claims submitted to the TRICARE Program that would impose any mandates on State, local, or tribal governments or the private sector that would result in an expenditure of \$140 million or more (adjusted for inflation) in any given year and that a full analysis under the Unfunded Mandates Reform Act is not necessary.

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

This rulemaking 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).

Executive Order 13132, “Federalism”

This proposed rule has been examined for its impact under E.O. 13132, and it does not contain 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 powers and responsibilities among the various levels of Government.

Therefore, consultation with State and local officials is not required.

List of Subjects

32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Mental health, Mental health parity, Military personnel.

32 CFR Part 200

Administrative practice and procedure, Fraud, Health care, Health insurance, Penalties.

For the reasons stated in the preamble, the Department of Defense proposes to amend 32 CFR subchapter M as set forth below:

PART 199—CIVILIAN HEALTH AND MEDICAL PROGRAM OF THE UNIFORMED SERVICES (CHAMPUS)

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 199.9 paragraph (f)(1)(ii) is revised to read as follows:

§ 199.9 Administrative remedies for fraud, abuse, and conflict of interest.

* * * * *

(f) * * *

(1) * * *

(ii) Administrative determination of fraud or abuse under CHAMPUS. If the Director, Defense Health Agency determines that a provider has committed fraud or abuse as defined in this part, the provider shall be excluded or suspended from CHAMPUS/TRICARE for a period of time determined by the Director. A final determination of an imposition of a civil monetary

penalty under 32 CFR part 200 shall constitute an administrative determination of fraud and abuse.

* * * * *

3. Add part 200 to read as follows:

PART 200—CIVIL MONEY PENALTY AUTHORITIES FOR THE TRICARE PROGRAM

Sec.

Subpart A—General Provisions

200.100 Basis and purpose.

200.110 Definitions.

200.120 Liability for penalties and assessments.

200.130 Assessments.

200.140 Determinations regarding the amount of penalties and assessments.

200.150 Delegation of authority.

Subpart B—Civil Money Penalties (CMPs) and Assessments for False or Fraudulent Claims and Other Similar Misconduct

200.200 Basis for civil money penalties and assessments.

200.210 Amount of penalties and assessments.

200.220 Determinations regarding the amount of penalties and assessments.

Subpart C—CMPs and Assessments for Anti-Kickback Violations

200.300 Basis for civil money penalties and assessments.

200.310 Amount of penalties and assessments.

200.320 Determinations regarding the amount of penalties and assessments.

Subpart D—CMPs and Assessments for Contracting Organization Misconduct

200.400 Basis for civil money penalties and assessments.

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Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55; 42 U.S.C. 1320a-7a.

Subpart A—General Provisions

§200.100 Basis and purpose.

(a) *Basis.* This part implements section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) (the Act).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who have committed an act or omission that violates one or more provisions of this part; and

(2) Sets forth the appeal rights of persons subject to a penalty and assessment.

§200.110 Definitions.

For purposes of this part, with respect to terms not defined in this section but defined in 32 CFR 199.2, the definition in such §199.2 shall apply. For purposes of this part, the following definitions apply:

Assessment means the amounts described in this part and includes the plural of that term.

Claim means an application for payment for an item or service under TRICARE/CHAMPUS.

Contracting organization means a public or private entity or other organization that has contracted with the Department to furnish, or otherwise pay for, items and services to TRICARE beneficiaries pursuant to chapter 55 of title 10, U.S. Code. The term expressly does not include entities with which the Department contracts to provide “managed care support” or “fiscal intermediary” services to the TRICARE program under Section 1097 of title 10, U.S. Code.

Defense Health Agency or DHA means the Director of the Defense Health Agency or designee.

Items and services or items or services includes without limitation, any item, device, drug, biological, supply, or service (including management or administrative

services), including, but not limited to, those that are listed in an itemized claim for program payment or a request for payment; for which payment is included in any TRICARE/CHAMPUS reimbursement method, such as a prospective payment system or managed care system; or that are, in the case of a claim based on costs, required to be entered in a cost report, books of account, or other documents supporting the claim (whether or not actually entered).

Knowingly means that a person, with respect to an act, has actual knowledge of the act, acts in deliberate ignorance of the act, or acts in reckless disregard of the act, and no proof of specific intent to defraud is required.

Material means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

Non-separately-billable item or service means an item or service that is a component of, or otherwise contributes to the provision of, an item or a service, but is not itself a separately billable item or service.

Office of Inspector General or OIG means the Office of Inspector General of the Department of Defense; the Defense Criminal Investigative Service (DCIS); or the Office of Inspector General for the Defense Health Agency.

Overpayment means any funds that a person receives or retains under TRICARE/CHAMPUS to which the person, after applicable reconciliation, is not entitled under such program.

Penalty means the amount described in this part and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Preventive care, for purposes of the definition of the term “remuneration” as set forth in this section and the preventive care exception to section 231(h) of HIPAA, means any service that—

(1) Is a prenatal service or a post-natal well-baby visit or is a specific clinical service covered by TRICARE; and

(2) Is reimbursable in whole or in part by TRICARE as a preventive care service.

Reasonable request, with respect to §200.200(b)(6), means a written request, signed by a designated representative of the OIG and made by a properly identified agent of the OIG during reasonable business hours. The request will include: A statement of the authority for the request, the person's rights in responding to the request, the definition of “reasonable request” and “failure to grant timely access” under this part, the deadline by which the OIG requests access, and the amount of the civil money penalty or assessment that could be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

Remuneration, for the purposes of this part, is consistent with the definition in section 1128A(i)(6) of the Social Security Act and includes the waiver of copayment, coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term “remuneration” does not include:

(1) The waiver of coinsurance and deductible amounts by a person, if the

waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts.

(2) Any permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary.

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented.

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by TRICARE, Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionately large in relationship to the value of the preventive care service (i.e., either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

(5) Items or services that improve a beneficiary's ability to obtain items and services payable by TRICARE, and pose a low risk of harm to TRICARE

beneficiaries and the TRICARE program by—

(i) Being unlikely to interfere with, or skew, clinical decision making;

(ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and

(iii) Not raising patient safety or quality-of-care concerns.

(6) The offer or transfer of items or services for free or less than fair market value by a person if—

(i) The items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) The items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under chapter 55 of title 10, U.S. Code.

(7) The offer or transfer of items or services for free or less than fair market value by a person, if—

(i) The items or services are not offered as part of any advertisement or solicitation;

(ii) The offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under chapter 55 of title 10, U.S. Code;

(iii) There is a reasonable connection between the items or services and the medical care of the individual; and

(iv) The person provides the items or services after determining in good faith that the individual is in financial need.

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty and/or assessment.

Separately billable item or service means an item or service for which an identifiable payment may be made under a Federal health care program, e.g., an itemized claim or a payment under a prospective payment system or other reimbursement methodology.

Should know, or should have known, means that a person, with respect to information, either acts in deliberate ignorance of the truth or falsity of the information or acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

TRICARE or TRICARE/CHAMPUS or CHAMPUS means any program operated under the authority of 32 CFR part 199.

§200.120 Liability for penalties and assessments.

(a) In any case in which it is determined that more than one person was responsible for a violation described in this part, each such person may be held separately liable for the entire penalty prescribed by this part.

(b) In any case in which it is determined that more than one person was responsible for a violation described in this part, an assessment may be imposed, when authorized, against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(c) Under this part, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of his or her agency. The provision in this paragraph (c) does not limit the underlying liability of the agent.

§200.130 Assessments.

The assessment in this part is in lieu of damages sustained by the Department because of the violation.

§200.140 Determinations regarding the amount of penalties and assessments.

(a) Except as otherwise provided in this part, in determining the amount of any penalty or assessment in accordance with this part, the DHA will consider the following factors—

(1) The nature and circumstances of the violation;

(2) The degree of culpability of the person against whom a civil money penalty and assessment is proposed. It should be considered an aggravating circumstance if the respondent had actual knowledge where a lower level of knowledge was required to establish liability (*e.g.*, for a provision that establishes liability if the respondent “knew or should have known” a claim was false or fraudulent, it will be an aggravating circumstance if the respondent knew the claim

was false or fraudulent). It should be a mitigating circumstance if the person took appropriate and timely corrective action in response to the violation. For purposes of this part, corrective action must include disclosing the violation to the DHA by initiating a self-disclosure and fully cooperating with the DHA's review and resolution of such disclosure;

(3) The history of prior offenses. Aggravating circumstances include, if at any time prior to the violation, the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or in connection with the delivery of a health care item or service;

(4) Other wrongful conduct. Aggravating circumstances include proof that the individual—or in the case of an entity, the entity itself; any individual who had a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in a sanctioned entity at the time the violation occurred and who knew, or should have known, of the violation; or any individual who was an officer or a managing employee (as defined in section 1126(b) of the Act) of such an entity at the time the violation occurred—engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to a government program or

in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance; and

(5) Such other matters as justice may require. Other circumstances of an aggravating or mitigating nature should be considered if, in the interests of justice, they require either a reduction or an increase in the penalty or assessment to achieve the purposes of this part.

(b)(1) After determining the amount of any penalty and assessment in accordance with this part, the DHA considers the ability of the person to pay the proposed civil money penalty or assessment. The person shall provide, in a time and manner requested by the DHA, sufficient financial documentation, including, but not limited to, audited financial statements, tax returns, and financial disclosure statements, deemed necessary by the DHA to determine the person's ability to pay the penalty or assessment.

(2) If the person requests a hearing in accordance with § 200.2002, the only financial documentation subject to review is that which the person provided to the DHA during the administrative process, unless the Administrative Law Judge (ALJ) finds that extraordinary circumstances prevented the person from providing the financial documentation to the DHA in the time and manner requested by the DHA prior to the hearing request.

(c) In determining the amount of any penalty and assessment to be imposed under this part the following circumstances are also to be considered—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by this part to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to or at the maximum permitted by this part to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should not be less than double the approximate amount of damages and costs (as defined by paragraph (e)(2) of this section) sustained by the United States, or any State, as a result of the violation.

(4) The presence of any single aggravating circumstance may justify imposing a penalty and assessment at or close to the maximum even when one or more mitigating factors is present.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, for its damages and costs, tangible and intangible, including, but not limited to, the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this part limits the authority of the Department or the DHA to settle any issue or case as provided by §200.1530 or to compromise any penalty

and assessment as provided by §200.1550.

(4) Penalties and assessments imposed under this part are in addition to any other penalties, assessments, or other sanctions prescribed by law.

§200.150 Delegation of authority.

The DHA is delegated authority from the Secretary to impose civil money penalties and, as applicable, assessments against any person who has violated one or more provisions of this part. The delegation of authority includes all powers to impose and compromise civil monetary penalties, assessments under section 1128A of the Act.

Subpart B—Civil Money Penalties (CMPs) and Assessments for False or Fraudulent Claims and Other Similar Misconduct

§200.200 Basis for civil money penalties and assessments.

(a) The DHA may impose a penalty, assessment against any person who it determines has knowingly presented, or caused to be presented, a claim that was for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that was part of a pattern or practice of claims based on codes that the person knew, or should have known, would result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known,

that the claim was false or fraudulent;

(3) An item or service furnished during a period in which the person was excluded from participation under 32 CFR 199.9(f) or by another Federal health care program (as defined in section 1128B(f) of the Act) to which the claim was presented;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified by a medical specialty board when he or she was not so certified; or

(5) An item or service that a person knew, or should have known was not medically necessary, and which is part of a pattern of such claims.

(b) The DHA may impose a penalty and, where authorized, an assessment against any person who it determines—

(1) Arranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in

Federal health care programs for the provision of items or services for which payment may be made under such a program;

(2) Orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program, in the case when the person knows, or should know, that a claim for such medical or other item or service will be made under such a program;

(3) Knowingly makes, or causes to be made, any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program, including contracting organizations, and entities that apply to participate as providers of services or suppliers in such contracting organizations;

(4) Knows of an overpayment and does not report and return the overpayment in accordance with section 1128J(d) of the Act;

(5) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(6) Fails to grant timely access to records, documents, and other material or data in any medium (including electronically stored information and any tangible thing), upon reasonable request, to the OIG, for the purpose of audits, investigations, evaluations, or other OIG statutory functions. Such failure to grant timely access means:

(i) Except when the OIG reasonably believes that the requested material is

about to be altered or destroyed, the failure to produce or make available for inspection and copying the requested material upon reasonable request or to provide a compelling reason why they cannot be produced, by the deadline specified in the OIG's written request; and

(ii) When the OIG has reason to believe that the requested material is about to be altered or destroyed, the failure to provide access to the requested material at the time the request is made.

§200.210 Amount of penalties and assessments.

(a) *Penalties.*¹ (1) Except as provided in this section, the DHA may impose a penalty of not more than \$20,000 for each individual violation that is subject to a determination under this subpart.

¹The penalty amounts in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74). Annually adjusted amounts are published at 32 CFR part 269.

(2) For each individual violation of §200.200(b)(1), the DHA may impose a penalty of not more than \$20,000 for each separately billable or non-separately-billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity.

(3) The DHA may impose a penalty of not more than \$100,000 for each false statement, omission, or misrepresentation of a material fact in violation of §200.200(b)(3).

(4) The DHA may impose a penalty of not more than \$100,000 for each false record or statement in violation of §200.200(b)(5).

(5) The DHA may impose a penalty of not more than \$20,000 for each item or service related to an overpayment that is not reported and returned in accordance with section 1128J(d) of the Act in violation of §200.200(b)(4).

(6) The DHA may impose a penalty of not more than \$30,000 for each day of failure to grant timely access in violation of §200.200(b)(6).

(b) *Assessments.* (1) Except for violations of §200.200(b)(1) and (3), the DHA may impose an assessment for each individual violation of §200.200, of not more than 3 times the amount claimed for each item or service.

(2) For violations of §200.200(b)(1), the DHA may impose an assessment of not more than 3 times—

(i) The amount claimed for each separately billable item or service provided, furnished, ordered, or prescribed by an excluded individual or entity; or

(ii) The total costs (including salary, benefits, taxes, and other money or items of value) related to the excluded individual or entity incurred by the person that employs, contracts with, or otherwise arranges for an excluded individual or entity to provide, furnish, order, or prescribe a non-separately-billable item or service.

(3) For violations of §200.200(b)(3), the DHA may impose an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement,

omission, or misrepresentation of material fact.

§200.220 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in §200.140—

(a) It should be considered a mitigating circumstance if all the items or services or violations included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or violations, and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items or services or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services, or the amount of the overpayment was \$50,000 or more;

(4) The violation resulted, or could have resulted, in patient harm, premature discharge, or a need for additional services or subsequent hospital admission; or

(5) The amount or type of financial, ownership, or control interest or the degree of responsibility a person has in an entity was substantial with respect to an action brought under §200.200(b)(3).

Subpart C—CMPs and Assessments for Anti-Kickback Violations

§200.300 Basis for civil money penalties and assessments.

The DHA may impose a penalty and an assessment against any person who it determines in accordance with this part has violated section 1128B(b) of the Act by unlawfully offering, paying, soliciting, or receiving remuneration to induce or in return for the referral of business paid for, in whole or in part, by TRICARE/CHAMPUS.

§200.310 Amount of penalties and assessments.

(a) *Penalties.*² The DHA may impose a penalty of not more than \$100,000 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under §200.300.

²The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 32 CFR part 269.

(b) *Assessments.* The DHA may impose an assessment of not more than 3 times the total remuneration offered, paid, solicited, or received that is subject to a determination under §200.300. Calculation of the total remuneration for purposes of an assessment shall be without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose.

§200.320 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in §200.140:

(a) It should be considered a mitigating circumstance if all the items, services, or violations included in the action brought under this part were of the

same type and occurred within a short period of time; there were few such items, services, or violations; and the total amount claimed or requested for such items or services was less than \$5,000.

(b) Aggravating circumstances include—

(1) The violations were of several types or occurred over a lengthy period of time;

(2) There were many such items, services, or violations (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of violations);

(3) The amount claimed or requested for such items or services or the amount of the remuneration was \$50,000 or more; or

(4) The violation resulted, or could have resulted, in harm to the patient, a premature discharge, or a need for additional services or subsequent hospital admission.

Subpart D—CMPs and Assessments for Contracting Organization

Misconduct

§200.400 Basis for civil money penalties and assessments.

The DHA may impose a penalty against any contracting organization that—

(a) Fails substantially to provide an enrollee with medically necessary items and services that are required (under chapter 55 of title 10, U.S. Code, applicable regulations, or contract with the Department of Defense) to be provided to such

enrollee and the failure adversely affects (or has the substantial likelihood of adversely affecting) the enrollee;

(b) Imposes a premium on an enrollee in excess of the amounts permitted under chapter 55 of title 10, U.S. Code; and

(c) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment by beneficiaries whose medical condition or history indicates a need for substantial future medical services, except as permitted by chapter 55 of title 10, U.S. Code.

§200.410 Amount of penalties and assessments for contracting organization.

(a) *Penalties.*³ (1) The DHA may impose a penalty of up to \$25,000 for each individual violation under §200.400, except as provided in this section.

³The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 32 CFR part 269.

(2) The DHA may impose a penalty of up to \$100,000 for each individual violation under §200.400(a)(3).

(b) *Additional penalties.* In addition to the penalties described in paragraph (a) of this section, the DHA may impose—

(1) An additional penalty equal to double the amount of excess premium charged by the contracting organization for each individual violation of §200.400(a)(2). The excess premium amount will be deducted from the penalty and returned to the enrollee.

(2) An additional \$30,000⁴ penalty for each individual expelled or not

enrolled in violation of §200.400(a)(3).

⁴This penalty amount is adjusted for inflation annually. Adjusted amounts are published at 32 CFR part 269.

§200.420 Determinations regarding the amount of penalties and assessments.

In considering the factors listed in §200.140, aggravating circumstances include—

(a) Such violations were of several types or occurred over a lengthy period of time;

(b) There were many such violations (or the nature and circumstances indicate a pattern of incidents);

(c) The amount of money, remuneration, damages, or tainted claims involved in the violation was \$15,000 or more; or

(d) Patient harm, premature discharge, or a need for additional services or subsequent hospital admission resulted, or could have resulted, from the incident; and

(e) The contracting organization knowingly or routinely engaged in any prohibited practice that acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization.

Subparts E-N [Reserved]

Subpart O—Procedures for the Imposition of CMPs and Assessments

§200.1500 Notice of proposed determination.

(a) If the DHA proposes a penalty and, when applicable, an assessment, as applicable, in accordance with this part, the DHA must serve on the respondent, in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure, written notice of the DHA's intent to impose a penalty and if applicable an assessment.

The notice will include—

(1) Reference to the statutory basis for the penalty and the assessment;

(2) A description of the violation for which the penalty, and assessment are proposed (except in cases in which the DHA is relying upon statistical sampling in accordance with §200.1580, in which case the notice shall describe those claims and requests for payment constituting the sample upon which the DHA is relying and will briefly describe the statistical sampling technique used by the DHA);

(3) The reason why such violation subjects the respondent to a penalty, and an assessment;

(4) The amount of the proposed penalty and assessment (where applicable);

(5) Any factors and circumstances described in this part that were considered when determining the amount of the proposed penalty and assessment;

(6) Instructions for responding to the notice, including—

(i) A specific statement of the respondent's right to a hearing; and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment, without right of appeal; and

(b) Any person upon whom the DHA has proposed the imposition of a penalty, and/or an assessment, may appeal such proposed penalty, and/or assessment to the Departmental Appeals Board in accordance with § 200.2002. The provisions of subpart P of this part govern such appeals.

(c) If the respondent fails, within the time period permitted, to exercise his or her right to a hearing under this section, any penalty, and/or assessment becomes final.

§200.1510 Failure to request a hearing.

If the respondent does not request a hearing within 60 days after the notice prescribed by §200.1500(a) is received, as determined by § 200.2002(c), by the respondent, the DHA may impose the proposed penalty and assessment, or any less severe penalty and assessment. The DHA shall notify the respondent in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure of any penalty and assessment that have been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, an assessment with respect to which he or she has not made a timely request for a hearing under § 200.2002.

§200.1520 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability for acts that violate this part has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part, a person is estopped from denying the essential elements of the criminal offense if the proceeding—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements; and

(2) Involves the same transactions as in the criminal action.

§200.1530 Settlement.

The DHA has exclusive authority to settle any issues or case without consent of the ALJ.

§200.1540 Judicial review.

(a) Section 1128A(e) of the Social Security Act authorizes judicial review of a penalty and an assessment that has become final. The only matters subject to judicial review are those that the respondent raised pursuant to § 200.2021, unless the court finds that extraordinary circumstances existed that prevented the respondent from raising the issue in the underlying administrative appeal.

(b) A respondent must exhaust all administrative appeal procedures established by the Secretary or required by law before a respondent may bring an action in Federal court, as provided in section 1128A(e) of the Social Security Act, concerning any penalty and assessment imposed pursuant to this part.

(c) Administrative remedies are exhausted when a decision becomes final in accordance with § 200.2021(j).

§200.1550 Collection of penalties and assessments.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of the Defense Health Agency.

(b) A penalty or an assessment imposed under this part may be compromised by the DHA and may be recovered in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The amount of penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States Government or a State agency to the person against whom the penalty or assessment has been assessed.

(d) Matters that were raised, or that could have been raised, in a hearing before an ALJ or in an appeal under section 1128A(e) of the Social Security Act may not be raised as a defense in a civil action by the United States to collect a penalty or assessment under this part.

§200.1560 Notice to other agencies.

Whenever a penalty and/or an assessment becomes final, the following organizations and entities will be notified about such action and the reasons for it: HHS Office of Inspector General, the appropriate State or local medical or professional association; the appropriate quality improvement organization; as appropriate, the State agency that administers each State health care program; the

appropriate TRICARE Contractor; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term-care ombudsman.

§200.1570 Limitations.

No action under this part will be entertained unless commenced, in accordance with §200.1500(a), within 6 years from the date on which the violation occurred.

§200.1580 Statistical sampling.

(a) In meeting the burden of proof in § 200.2015, the DHA may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment, as described in this part, that were presented, or caused to be presented, by the respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment, as described in this part.

(b) Once the DHA has made a prima facie case, as described in paragraph (a) of this section, the burden of production shall shift to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The DHA will then be given the opportunity to rebut this evidence.

(c) Where the DHA establishes a number and amount of claims subject to penalties using a statistical sampling study, the DHA may use the results of the study to extrapolate a total amount of overpaid funds to be collected pursuant to 32

CFR 199.11.

§§200.1590-200.1990 [Reserved]

Subpart P—Appeals of CMPs and Assessments

§200.2001 Definitions.

For purposes of this subpart, the following definitions apply:

Civil money penalty cases refer to all proceedings arising under any of the statutory bases for which the DHA has been delegated authority to impose civil money penalties under TRICARE.

DAB refers to the Department of Health and Human Services, Departmental Appeals Board or its delegate, or other administrative appeals decision maker designated by the Director, DHA.

§200.2002 Hearing before an ALJ.

(a) A party sanctioned under any criteria specified in this part may request a hearing before an ALJ.

(b) In civil money penalty cases, the parties to the proceeding will consist of the respondent and the DHA.

(c) The request for a hearing will be made in writing to the DAB; signed by the petitioner or respondent, or by his or her attorney; and sent by certified mail. The request must be filed within 60 days after the notice, provided in accordance with §200.1500, is received by the petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

(d) The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.

(e) The ALJ will dismiss a hearing request where—

(1) The petitioner's or the respondent's hearing request is not filed in a timely manner;

(2) The petitioner or respondent withdraws his or her request for a hearing;

(3) The petitioner or respondent abandons his or her request for a hearing; or

(4) The petitioner's or respondent's hearing request fails to raise any issue which may properly be addressed in a hearing.

§200.2003 Rights of parties.

(a) Except as otherwise limited by this part, all parties may—

(1) Be accompanied, represented and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this part;

(4) Agree to stipulations of fact or law which will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of section 206 of title II of the Act, which authorizes the Secretary to specify or limit these fees.

§200.2004 Authority of the ALJ.

(a) The ALJ will conduct a fair and impartial hearing, avoid delay, maintain order and assure that a record of the proceeding is made.

(b) The ALJ has the authority to—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this part;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact; and

(13) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone.

(c) The ALJ does not have the authority to—

(1) Find invalid or refuse to follow Federal statutes or regulations or secretarial delegations of authority;

(2) Enter an order in the nature of a directed verdict;

(3) Compel settlement negotiations;

(4) Enjoin any act of the Secretary; or

(5) Review the exercise of discretion by the DHA to impose a CMP or assessment under this part.

§200.2005 Ex parte contacts.

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§200.2006 Prehearing conferences.

(a) The ALJ will schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this part;

(9) The time and place for the hearing;

(10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings; and

(11) Potential settlement of the case.

(c) The ALJ will issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§200.2007 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term documents includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document, except that requested

data stored in an electronic data storage system will be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section will not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request will either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part will be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. (The party receiving a request for production may also file a motion for protective order any time prior to the date the production is due.)

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

- (i) Is irrelevant;
- (ii) Is unduly costly or burdensome;
- (iii) Will unduly delay the proceeding; or
- (iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

§200.2008 Exchange of witness lists, witness statements and exhibits.

(a) At least 15 days before the hearing, the ALJ will order the parties to exchange witness lists, copies of prior written statements of proposed witnesses and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with §200.2016.

(b)(1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ will determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of such evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure to timely exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief:

(i) The testimony of any witness whose name does not appear on the witness list; and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of such evidence would cause substantial prejudice to the objecting party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence,

or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless another party objects within a reasonable period of time prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§200.2009 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of an individual in accordance with paragraph (a) of this section may also require the individual (whether or not the individual is a party) to produce evidence authorized under §200.2007 at or prior to the hearing.

(c) When a subpoena is served by a respondent or petitioner on a particular individual or particular office of the DHA, the DHA may comply by designating any of its representatives to appear and testify.

(d) A party seeking a subpoena will file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. Such request will:

(1) Specify any evidence to be produced;

(2) Designate the witnesses; and

(3) Describe the address and location with sufficient particularity to permit such witnesses to be found.

(e) The subpoena will specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena will serve it by delivery to the individual named, or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(h) The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in section 205(e) of the Social Security Act (42 U.S.C. 405(e)).

§200.2010 Fees.

The party requesting a subpoena will pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage will accompany the subpoena when served, except that when a subpoena is issued on behalf of the DHA, a check for witness fees and mileage need not accompany the subpoena.

§200.2011 Form, filing and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ will include an original and two copies.

(2) Every pleading and paper filed in the proceeding will contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper will be signed by, and will contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Secretary will, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document will be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service will be made upon such attorney in lieu of the party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, will be proof of service.

§200.2012 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government will be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response. This paragraph (c) does not apply to requests for hearing under §200.2002.

§200.2013 Motions.

(a) An application to the ALJ for an order or ruling will be by motion. Motions will state the relief sought, the authority relied upon and the facts alleged, and will be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions will be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ will make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§200.2014 Sanctions.

(a) The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. Such sanctions will reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(1) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(2) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(3) Striking pleadings, in whole or in part;

- (4) Staying the proceedings;
- (5) Dismissal of the action;
- (6) Entering a decision by default; and
- (7) Refusing to consider any motion or other action that is not filed in a timely manner.

(b) In civil money penalty cases commenced under section 1128A of the Social Security Act or under any provision which incorporates section 1128A(c)(4) of the Social Security Act, the ALJ may also order the party or attorney who has engaged in any of the acts described in paragraph (a) of this section to pay attorney's fees and other costs caused by the failure or misconduct.

§200.2015 The hearing and burden of proof.

(a) The ALJ will conduct a hearing on the record in order to determine whether the petitioner or respondent should be found liable under this part.

(b) With regard to the burden of proof in civil money penalty cases under this part—

(1) The respondent or petitioner, as applicable, bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and

(2) The DHA bears the burden of going forward and the burden of persuasion with respect to all other issues.

(c) The burden of persuasion will be judged by a preponderance of the evidence.

(d) The hearing will be open to the public unless otherwise ordered by the ALJ for good cause shown.

(e)(1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under §200.2008, additional items and information, including aggravating or mitigating circumstances

that arose or became known subsequent to the issuance of the notice letter, may be introduced by either party during its case-in-chief unless such information or items are—

(i) Privileged; or

(ii) Deemed otherwise inadmissible under §200.2017.

(2) After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged in accordance with §200.2008.

§200.2016 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing will be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts which has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to all other parties along with the last known address of such witnesses, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing will be exchanged as provided in §200.2008.

(c) The ALJ will exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid repetition or needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ will permit the parties to conduct such cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual engaged in assisting the attorney for the Inspector General (IG).

§200.2017 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. Such evidence is admissible regardless of whether the crimes,

wrongs or acts occurred during the statute of limitations period applicable to the acts which constitute the basis for liability in the case, and regardless of whether they were referenced in the DHA's notice sent in accordance with §200.1500.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

(j) The ALJ may not consider evidence regarding the issue of willingness and ability to enter into and successfully complete a corrective action plan when such evidence pertains to matters occurring after the submittal of the case to the Secretary. The determination regarding the appropriateness of any corrective action plan is not reviewable.

§200.2018 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§200.2019 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ will fix the time for filing such briefs which are not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the

stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§200.2020 Initial decision.

(a) The ALJ will issue an initial decision, based only on the record, which will contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase or reduce the penalties, assessment proposed or imposed by the DHA.

(c) The ALJ will issue the initial decision to all parties within 120 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. The decision will be accompanied by a statement describing the right of any party to file a notice of appeal with the DAB and instructions for how to file such appeal. If the ALJ fails to meet the deadline contained in this paragraph, he or she will notify the parties of the reason for the delay and will set a new deadline.

(d) Except as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(e) If an extension of time within which to appeal the initial decision is granted under §200.2021(a), except as provided in §200.2022(a), the initial decision will become final and binding on the day following the end of the extension period.

§200.2021 Appeal to DAB.

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may

extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the DAB, the ALJ will forward the record of the proceeding to the DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

(d) There is no right to appear personally before the DAB or to appeal to the DAB any interlocutory ruling by the ALJ, except on the timeliness of a filing of the hearing request.

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty or assessment determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) Within 120 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB's decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty or assessment remanded by the ALJ, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) Any petition for judicial review must be filed within 60 days after the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of the DAB will be sent by certified mail, return receipt requested, to the General Counsel of the DHA. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the General Counsel of the DHA receives two or more petitions within 10 days after the DAB issues its decision, the General Counsel of the DHA will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

§200.2022 Stay of initial decision.

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b)(1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the

ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

§200.2023 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives or TRICARE contractors is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the DAB inconsistent with substantial justice. The ALJ and the DAB at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

Dated: April 26, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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