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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: Final rule.

SUMMARY: This final rule implements civil money penalties authority provided to all Federal health care programs, including the TRICARE program, under the Social Security Act. This authority allows the Secretary of Defense as the administrator of a Federal health care program to impose civil money 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 final rule establishes a program within the DoD to impose CMPs for certain unlawful conduct in the TRICARE program. To the extent applicable, this final rule adopts the Department of Health and Human Service's (HHS's) well-established CMP rules and procedures. The program to impose CMPs within TRICARE is called the Military Health Care Fraud and Abuse Prevention Program. The Defense Health Agency (DHA) shall be the agency within the DoD responsible for administering the Military Health Care Fraud and Abuse Prevention Program.

DATES: This rule is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Overview

A. Purpose of the Final Rule

The DHA, the agency of the DoD 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 inhibited DHA's mission. The Department of Justice (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, but 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. Congress has provided Federal departments responsible for a Federal health care program with the authority under section 1128A(m) of the Social Security Act (42 U.S.C. 1320a–7a(m)) to initiate administrative proceedings to impose CMPs against those who commit fraud and abuse in their respective Federal health care program. The HHS implemented this authority many years ago and has a well-developed process for imposition of CMPs penalties against those who commit fraud and abuse in the Medicare Program.

This final rule implements the same authority used by HHS under section 1128A(m) of the Social Security Act (42 U.S.C. 1320a–7a(m)) to establish a program to initiate administrative

proceedings to impose CMPs against those who commit fraud and abuse in the TRICARE Program.

The purpose of this final rule implementing CMP authority under section 1128A of the Social Security Act 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. Summary of Major Provisions

For the most part, this final rule incorporates the provisions of the May 1, 2019, proposed rule (84 FR 18437). A brief description of the provisions of this final rule follow.

This final rule establishes CMP regulations at 32 CFR part 200 to implement authority provided to the DoD under section 1128A of the Social Security Act, as amended. The CMP regulations follow HHS's process and procedure for imposing CMPs, as well as HHS's methodology for calculating the amount of penalties and assessments. Accordingly, the numerical provisions of 32 CFR part 200 directly correspond to HHS's numerical provisions at 42 CFR part 1003. Following this organizational construct, the 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, procedures for the imposition of CMPs and assessments, judicial review, time limitations for CMPs and assessments, statistical sampling, and appeals.

C. Legal Authority for this Program

The specific legal authority authorizing the DoD 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 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 applicability to conduct only involving Medicare and Medicaid; therefore, this rule implements all CMP authorities under section 1128A that are not specifically limited to Medicare, Medicaid, or other HHS-exclusive authority.

II. Regulatory History

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 the Health Insurance Portability and Accountability Act of 1996 (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 Money 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 of Health and Human Services 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). The Secretary of HHS delegated the CMPL's authorities to HHS-OIG. 53 FR 12993 (April 20, 1988). Since 1981, Congress 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, Congress expanded the CMPL and the scope of exclusion to apply to all Federal health care programs. Section 231 of 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 in the TRICARE Program. 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 or agency.

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.

III. Public Comments

The proposed rule titled "Civil Money Penalties and Assessments under the Military Health Care Fraud and Abuse Prevention Program" published in the Federal Register on May 1, 2019 (84 FR 18437-18452), and provided a 60-day public comment period. DoD received a total of 17 timely-filed public comments from three responders: a current TRICARE Managed Care Support Contractor (MCSC), a professional association of firms that sells commercial services and products to the Federal Government, and an interested party. The comments included both broad concerns about the issuance of these CMP regulations, and more detailed concerns on specific aspects of the CMP provisions. Set forth below is a synopsis of the comments received, our response to those comments, and clarifications being made to the regulations at 32 CFR parts 199 and 200.

***Comment 1*:** One commenter argues Congress has not expressly authorized the extensive administrative process within DoD to apply CMP to TRICARE, as contemplated in the proposed rule's new part 200.

Response: We disagree. In Section 231 of the HIPAA of 1996, Congress expressly made CMP authority applicable to all Federal health care programs and expressly authorized all Federal health care programs develop their own CMP Programs using the authority it provided.

***Comment 2*:** One commenter expressed concern the proposed rule, which the commenter stated, "appears to be unnecessary to protect DoD against fraud by manufacturers and distributors of drugs and medical devices" could harm beneficiaries' access to critical care. The commenter further stated that DoD currently has tools to pursue fraud when these products are

procured or provided by its contractors and those authorities are more simple and less risky, rather than implementing a CMP program.

***Response*:** We disagree. The protection of TRICARE beneficiaries and ensuring they are getting services and supplies that are medically necessary and appropriate, as well as protecting the program from fraud and abuse, is our primary concern and the core intent of this program. Current administrative authority includes provider education, prepayment and post-payment review, limited overpayment recovery, temporary claims payment suspensions, exclusions, and removal from network. The DHA is not currently able to impose CMPs against those who commit fraud in the TRICARE Program. This authority provided by Congress will serve as a strong deterrent against fraud and abuse in the TRICARE Program. CMPs are a well-established deterrent against healthcare fraud, utilized by HHS for many years. CMPs may be imposed in addition to any other penalties that may be prescribed by law and will not conflict with current authority.

***Comment 3*:** A commenter expressed concern the proposed rule is unclear as to how DHA will apply the "knowingly and intentionally" standard, especially as it lacks the experience of HHS to investigate and make determinations of health care fraud.

***Response*:** The TRICARE CMP proposed rule, as well as HHS CMP rules, use a "knowingly" standard for imposition of CMPs and not a "knowingly and intentionally" standard. The term "intentionally" does not appear in the TRICARE proposed rule. As we stated in the preamble to the proposed rule, we will be following HHS guidance to eliminate any confusion. For purposes of this final rule, the term "knowingly" is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. 3729(b)) and HHS's CMP final rule (65 FR 24416). As stated in the proposed rule, "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. We believe this definition is sufficiently clear and conduct implicating CMP law which includes this this requisite intent will be evaluated for imposition of a CMP.

TRICARE does not lack experience regarding fraud and abuse. TRICARE has an established, centralized, and well-connected fraud and abuse program within the TRICARE Program. *See* https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Quality-And-Safety-of-Healthcare/Program-Integrity. Title 32 CFR 199.9 provides fraud and abuse regulations under the TRICARE program.

***Comment 4*:** One commenter stated that although the preamble to the proposed rule indicates DoD may coordinate with DOJ, there is no requirement for such coordination, and DoD may proceed with determining health care fraud without applying the standards that would govern TRICARE claims if handled by DOJ. As noted, it is unclear how DHA would interpret knowing and intentional conduct in imposing a civil money penalty under the rule.

***Response*:** The authority provided by Congress at 1128A(c)(1) of the Social Security Act (42 U.S.C. 1320a–7a(c)(1)) requires the DoD to obtain consent of DOJ prior to imposing a CMP. The DoD will coordinate closely with DOJ, Defense Criminal Investigative Service (DCIS), and HHS-OIG. Actions will be coordinated with DOJ before an initial determination action is made to prevent any concurrent DHA and False Claims Act (FCA) cases (including qui tam cases), and avoid inconsistent outcomes or the occurrence of duplicative penalties, where appropriate.

***Comment 5*:** One commenter stated that of particular concern is the proposed rule does not state whether it would follow an internal DOJ memorandum [Memorandum from the

Associate Attorney General, *Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases*, January 25, 2018] that prohibits using noncompliance with agency, sub-regulatory guidance as a basis for proving knowing violations of law in civil enforcement proceedings.

***Response*:** The memorandum cited by the commenter is an internal DOJ memorandum applicable to affirmative civil enforcement actions brought by the DOJ. The memorandum states the memorandum "is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal." The memorandum has no effect outside of DOJ components and employees. Therefore, any reference to the DOJ memorandum referred to by the commenter in the proposed rule would have been inappropriate. However, as stated above, the DoD will coordinate closely with DOJ, DCIS, and HHS-OIG. Actions will be coordinated with DOJ, as required by 1128A(c)(1) of the Social Security Act, before an initial determination action is made to prevent any concurrent DHA and FCA cases (including qui tam cases), and avoid inconsistent outcomes or the occurrence of unintended duplicative penalties, where appropriate.

***Comment 6*:** One commenter objected to the use of a statistical sampling study as the basis for proving the number and amount of claims subject to assessment of civil money penalties (proposed 32 CFR 200.1580).

***Response*:** Statistical sampling is a longstanding proven method for calculating overpayments, which has been upheld in the Courts. See *Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914 (D.C. Cir. 1991), *cert.* denied, 402 U.S. 1091 (1992). Statistical sampling is generally accepted as a basis of recoupment for Federal health care programs. One of the reasons that courts permit parties to use statistical sampling in cases regarding fraud against the

government is that, there is a "fairly low risk of error," if appropriate methods are followed. Accordingly, when appropriate methods are followed, we believe statistical sampling is a necessary and valid basis to establish number and amount of claims subject to assessment of civil money penalty cases.

***Comment 7*:** A commenter stated that in the context of the TRICARE Retail Refund Program, the CMP prohibiting a false statement, omission, or misrepresentation of material fact in a contract to participate as a supplier of under a Federal health care program would overlap with the responsibility of the Department of Veterans Affairs (VA) to administer the Veterans Health Care Act (VHCA) and would usurp the VA's authority if applied to the pricing required by the VHCA. The commenter further states the VA is the sole agency responsible for administering the Federal Supply Schedule (FSS) contract and ensuring the accuracy of statutory and contract prices for covered drugs on behalf of the DoD. The commenter states that in their view it is important to not have overlapping authority to avoid inconsistent interpretation and application of the VHCA.

***Response*:** A DoD Retail Refund Pricing Agreement is signed and executed between the manufacturer and the DHA. Where a manufacturer makes false statement, omission, or misrepresentation of material fact in a contract to participate as a supplier under a Federal health care program, such as an agreement under the TRICARE Retail Refund Program pursuant to 10 U.S.C. 1074g(f), that conduct may implicate CMP law under 32 CFR 200.200(b)(3). We do not agree an imposition of a CMP based on conduct in violation of the law with the consent of DOJ and in close coordination with DCIS, VA, and HHS-OIG would usurp any of the VA's authority. CMPs may be imposed in addition to any other penalties that may be prescribed by law and will not limit VA's authority. Additionally, as stated in 32 CFR 199.21(q)(4), "[i]n the case of the

failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, [TRICARE Management Activity] TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law." We believe CMPs will create a strong deterrent against such conduct.

***Comment 8*:** A commenter expressed concerns TRICARE should not allow overpayments associated with the TRICARE Retail Refund Program because laws already exist for the return of an overpayment. The commenter also notes calculation of the overpayment amount related to the TRICARE Retail Refund Program is very complicated and can result in frequent and routine restatement of amounts. Therefore, the commenter reiterates concern the proposed CMP law will result in overlapping authority between the DHA and the VA potentially resulting in inconsistent demands for differing overpayment amounts.

***Response*:** We believe CMPs offer a great deterrent value over current authorities. Congress's intent provided under to 1128A(a) of the Social Security Act, was that CMPs are "in addition to any other penalties that may be prescribed by law." CMPs are complementary to existing regulation under 32 CFR 199.21(q)(4), which provides "[i]n the case of the failure of a manufacturer of a covered drug to honor a requirement of this paragraph (q) or to honor an agreement under this paragraph (q), the Director, TMA, in addition to other actions referred to in this paragraph (q), may take any other action authorized by law." Additionally, refunds related to the TRICARE Retail Refund Program are subject to adjustments and reversals of amounts. However, once the overpayment is validated by the DHA and payment has not been made in accordance with requirements, the manufacturer could be subject to a CMP for retaining funds under TRICARE/CHAMPUS to which the manufacturer, after applicable reconciliation, is not entitled. The DoD will coordinate with DOJ, VA, DCIS, and HHS-OIG, when considering the

imposition of a CMP. The CMP Program is an enforcement mechanism and will not establish the amount to be refunded to the TRICARE Program under the TRICARE Retail Refund Program, but rather will rely on current processes and procedures to establish a validated overpayment.

***Comment 9*:** One commenter stated the TRICARE regulation that governs the retail refund program, 32 CFR 199.21(q), requires prescription rebate amounts invoiced by manufacturers be treated as overpayments under 32 CFR 199.11. The commenter argues these rebate amounts, which were never paid to the manufacturer by DoD should not qualify as an overpayment and should not be refunded. The commenter stated DoD should exclude funds pursuant to the TRICARE Retail Refund Program under §199.21(q) from the proposed rule.

***Response*:** Under 32 CFR 199.21(q)(3)(iii), "a refund due under this paragraph (q) is subject to §199.11 of this part and will be treated as an erroneous payment under that section." Title 32 CFR 199.11 governs overpayments. The proposed rule defines overpayments as "any funds that a person receives or retains under TRICARE/CHAMPUS to which the person, after applicable reconciliation, is not entitled under such program." Retaining funds subject to rebate under the TRICARE Retail Refund Program are overpayments, therefore, the DHA does not consider it appropriate to exclude refunds required under §199.21(q) from the jurisdiction of the CMP regulations.

***Comment 10*:** A commenter stated the proposed rule does not address restatements to the VA under the TRICARE Retail Refund Program, nor does it clarify when knowledge of an additional refund caused by a restated rebate amount would trigger an overpayment. The commenter indicated a restated amount requires validation by the VA and seeks clarification that

knowledge of an overpayment under the TRICARE program cannot begin until restated values are established by the VA.

***Response*:** The TRICARE Retail Refund Program operates independently from other Federal Pricing Programs, such that, agreements with or participation under other programs has no bearing on a pharmaceutical agent's covered status or refund eligibility. Covered drug status is determined by VA, they are the lead agency for providing this information to DHA. When calculating refunds, DoD uses non-Federal Average Manufacturer Price (FAMP) and Federal Ceiling Price (FCP) amounts provided by the VA. DHA will request from the VA the current annual FCP and the annual non-FAMP from which it was derived prior to compiling each quarterly invoice. The pricing data obtained will be applicable to all prescriptions filled during each respective quarter. If a manufacturer believes the data provided by the VA to DHA are erroneous, it is the manufacturer's responsibility to contact the VA to address any restatements or corrections.

The DHA and the TRICARE Program validate overpayments independently from the VA. As stated above, the CMP program will not establish the amount to be refunded to the TRICARE Program under the TRICARE Retail Refund Program, but rather will rely on current processes and procedures to establish a final, validated amount. The DHA will provide Demand Letters to Manufacturers notifying them of amounts due.

***Comment 11*:** One commenter stated TRICARE providers do not necessarily participate in Centers for Medicare and Medicaid Services (CMS) programs. Certain specialties, such as Applied Behavioral Analysis, may not even be covered under the programs currently subject to CMPs. Imposing such restrictions on specialty providers who have historically not participated in CMP programs could be have a significant impact on the network and affect access to care.

***Response*:** All providers who submit claims to the TRICARE program in violation of the CMP law shall be subject to penalties. The majority of providers have at some point submitted claims to Medicare and have been subject to almost identical rules for not submitting claims involving fraud or abuse for many years in the Medicare Program. Such restrictions on all providers, including specialty providers, are standard for submitting claims in a Federal healthcare program. Establishment of this program under authority provided by Congress is entirely appropriate for the protection of TRICARE beneficiaries and to ensure that they receive only medically necessary and appropriate services and supplies.

***Comment 12*:** The commenter also stated current statistical sampling methodology under the TRICARE program differs from CMS, which could be called into question since there is no precedence for collecting CMP or an extrapolated loss. The commenter notes recent draft changes to policy rely on the TRICARE Managed Care Support Contractor to determine statistical sampling methodology. The commenter states this does not follow CMS precedent and questions whether it is DHA's intent to change this process to mirror CMS?

***Response*:** We do not agree current statistical methodology under the TRICARE Program differs from CMS. As stated in the proposed rule at 32 CFR 200.1580, TRICARE's process for conducting a statistical sampling case will be "based upon an appropriate sampling and computed by valid statistical methods [.]" TRICARE will not have its MCSC perform statistical sampling involving CMPs. Any changes in policy requirements in effect regarding the MCSC's responsibility for statistical sampling do not involving statistical sampling under the CMP Program. HHS OIG also does not use CMS contractors to perform statistical sampling for its CMP cases. As stated above, there is precedence for utilizing statistical sampling as evidence of the number and amount of claims and/or requests for payment. Use of statistical sampling has

been upheld in the Courts and is regularly used by HHS within its CMP program. TRICARE will follow a similar process to that of CMS and HHS.

***Comment 13*:** A commenter stated the proposed rule indicates the rule would apply to providers and suppliers who commit fraud and abuse, which are both criminal and civil violations. The commenter stated this would require the justice system to make this determination. The commenter asked if the Administrative Law Judge (ALJ) make this determination.

***Response*:** TRICARE's CMP rule implements authority provided in section 1128A of the Social Security Act to initiate administrative proceedings to impose civil money penalties against those who commit fraud and abuse in the Medicare Program. This authority at 1128A(c)(1) of the Social Security Act (42 U.S.C. 1320a–7a(c)(1)) requires the DoD to obtain consent of DOJ prior to imposing a CMP. The DHA will make this determination pursuant to the authority under 1128A in close coordination with DOJ, DCIS, and HHS-OIG. Administrative Law Judges are required under 1128A(e) of the Social Security Act. The ALJ will make the final agency determination on appeals filed with the DHA.

***Comment 14*:** A commenter questioned whether the MCSC will continue to develop and submit cases of potential fraud within current thresholds in view of the proposed rule and whether those cases will be the basis for the imposition of a CMP.

***Response*:** The MCSC will continue to develop and submit cases under Section C of current contracts and in accordance with TRICARE Operations Manual, Chapter 13. The CMP Program will have no impact on current contracts with TRICARE's MCSC.

***Comment 15*:** The commenter also asked whether it is the Government's intent to amend MCSC contracts to now include the Military Health Care Fraud and Abuse Prevention Program

within their scope of services or will this be bid separately? If bid separately, the administrator of this program would need to work closely with MCSC to ensure both entities are prepared to address inquiries, appeals, grievances, litigation, customer dissatisfaction, etc. In addition, the data and facts from which each CMP case is based on would need to originate from the MCSC, who provides the services and process claims for payment. Has this been considered? The effort required to handle inquiries, establish operations, address legal actions, field calls, respond to complaints and other administrative support functions would be considerable. CMP actions taken against providers could cause reputational impact to the program and its contractors and subcontractors, adding reputational risk.

***Response*:** DHA does not intend to amend its current MCSC contracts to incorporate any additional requirements involving CMP authority. The DHA will operate its CMP Program independently of the MCSC. The CMP program will have no impact on case referral requirements with current TRICARE MCSCs.

***Comment 16*:** A commenter stated that under the current model utilized by TRICARE's MCSCs, claim audits reveal overpayments on a claim line basis, which can be recovered. Credits are issued to the Government with an accompanying TRICARE encounter data (TED) record update to ensure proper reconciliation of payments. Extrapolated loss collection cannot be credited back to an individual claims and therefore would not result in a TED updates either. Will extrapolated loss collection be credited to another account?

Response: The process in which TRICARE/DHA applies settlement dollars back to the program will remain the same. They are not applied at the claim level line and TED records are not updated.

***Comment 17*:** One commenter stated they believed the creation of a CMP program under TRICARE was a great idea. The commenter stated that from the commenter's perspective civilian providers and suppliers try to take advantage of the military system and having this regulation in place would in their view prevent fraud and abuse in the TRICARE program.

***Response*:** We agree. As stated above, the protection of TRICARE beneficiaries and ensuring that they are getting services and supplies that are medically necessary and appropriate, and protect the program which is funded by taxpayer dollars to deter again fraud and abuse and taking advantage of the program is at the core of this program. This authority provided by Congress will serve as a strong deterrent against fraud and abuse in the TRICARE Program.

IV. Summary of Changes from the Proposed Rule

We are deleting subpart D of the proposed rule, §§200.400, 200.410, and 200.420, involving contract organization misconduct from the Military Health Care Fraud and Abuse Prevention Program. TRICARE contracting organizations are structured differently than Medicare, and therefore, subpart D of the proposed rule is largely inapplicable to TRICARE and will not be incorporated into the final rule.

IV. Regulatory Analysis

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

E.O.s 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). E.O. 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 the economic threshold of $100 million or more. This final rule is designed to implement statutory provisions, authorizing the DoD to impose CMPs. The vast majority of providers and Federal health care programs would be minimally impacted, if at all, by this final rule. Accordingly, the aggregate economic effect of these regulations would be significantly less than $100 million.

Executive Order 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 Office of Management and Budget (OMB) Circular A–4 and Office of Information and Regulatory Affairs guidance on implementing E.O. 13771, this final rule does not involve regulatory costs subject to E.O. 13771.

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 final 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 final 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 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 final rules implement statutory authority to impose CMPs on claims submitted to the TRICARE Program is a similar manner as implemented by the Department of Health and Human Services in the Medicare Program. It has been determined there are no significant costs associated with the 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 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 final 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 amends 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(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 of the Defense Health Agency determines a provider 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 money penalty (CMP) 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.

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.

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 the Health Insurance Portability and Accountability Act of 1996 (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 disproportionally 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 money 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;

(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 $20,504 for each individual violation that is subject to a determination under this subpart.

[1]The 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. The maximum penalty amount is based on the most recent statutory adjustment included in the Bipartisan Budget Act of 2018 and includes the cost of living multiplier for 2019, based on the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October 2018, not seasonally adjusted, is 1.02522, as indicated in Office of Management and Budget (OMB) Memorandum M-19-04.

(2) For each individual violation of §200.200(b)(1), the DHA may impose a penalty of not more than $20,504 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 $100,522 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 $100,522 for each false record or statement in violation of §200.200(b)(5).

(5) The DHA may impose a penalty of not more than $20,504 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 $30,757 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 $100,522 for each offer, payment, solicitation, or receipt of remuneration that is subject to a determination under §200.300.

[2]The 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. The maximum penalty amount is based on the most recent statutory adjustment included in the Bipartisan Budget Act of 2018 and includes the cost of living multiplier for 2019, based on the CPI-U for the month of October 2018, not seasonally adjusted, is 1.02522, as indicated in OMB Memorandum M-19-04.

(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.

Subparts D-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; and

(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.

(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: Department of Health and Human Service (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 section 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 under this part, 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 in this part 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 (c), 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: September 14, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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