Burn'' is used to refer to multiple areas in the United States. Therefore, wine bottlers using ''The Burn,'' standing alone, in a brand name or in another label reference on their wines will not be affected by the establishment of this AVA.

The establishment of The Burn of Columbia Valley AVA will not affect the existing Columbia Valley AVA, and any bottlers using ''Columbia Valley'' as an appellation of origin or in a brand name for wines made from grapes grown within the Columbia Valley will not be affected by the establishment of this new AVA. The establishment of The Burn of Columbia Valley AVA will allow vintners to use ''The Burn of Columbia Valley'' and ''Columbia Valley'' as appellations of origin for wines made primarily from grapes grown within The Burn of Columbia Valley AVA if the wines meet the eligibility requirements for these appellations.

Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this final rule.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Subpart C is amended by adding § 9.276 to read as follows:

§ 9.276 The Burn of Columbia Valley.

(a) *Name.* The name of the viticultural area described in this section is ''The Burn of Columbia Valley''. For purposes of part 4 of this chapter, ''The Burn of Columbia Valley'' is a term of viticultural significance.

(b) *Approved maps.* The four United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of The Burn of Columbia Valley viticultural area are titled:

(1) Sundale NW, OR–WA, 2017;

(2) Goodnoe Hills, WA, 2017;

(3) Dot, WA, 2017; and

(4) Sundale, WA–OR, 2017.

(c) *Boundary.* The Burn of Columbia Valley viticultural area is located in Klickitat County in Washington. The boundary of The Burn of Columbia Valley viticultural area is as described below:

(1) The beginning point is on the Sundale NW map, at the intersection of the Columbia River and the east shore of Paterson Slough. From the beginning point, proceed northerly along the east shore of Paterson Slough to its junction with Rock Creek, and continuing northeasterly along Rock Creek to its intersection with the boundary of the Yakima Nation Trust Land; then

(2) Proceed south, then east, then generally northeasterly along the boundary of the Yakima Nation Trust Land, crossing onto the Goodnoe Hills map, to the intersection of the Trust Land boundary with Kelley Road; then

(3) Proceed north in a straight line to the intersection with the main channel of Chapman Creek; then

(4) Proceed southeasterly (downstream) along Chapman Creek, crossing over the Dot map and onto the Sundale map, to the intersection of Chapman Creek with its southernmost tributary; then

(5) Proceed due east in a straight line to the creek running through Old Lady Canyon; then

(6) Proceed southerly along the creek to its intersection with the northern shoreline of the Columbia River; then

(7) Proceed westerly along the northern shoreline of the Columbia River, returning to the beginning point.

Signed: January 4, 2021.

Mary G. Ryan,

Administrator.

Approved: January 5, 2021.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. 2021–12771 Filed 6–16–21; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 45

[Docket ID: DOD–2021–OS–0047]

RIN 0790–AL22

Medical Malpractice Claims by Members of the Uniformed Services

AGENCY: Department of Defense (DoD) Office of General Counsel, DoD.

ACTION: Interim final rule.

SUMMARY: This interim final rule implements requirements of the National Defense Authorization Act (NDAA) for Fiscal Year 2020 permitting members of the uniformed services or their authorized representatives to file claims for personal injury or death caused by a Department of Defense (DoD) health care providers s in certain military medical treatment facilities. Because Federal courts do not have jurisdiction to consider these claims, DoD is issuing this rule to provide uniform standards and procedures for considering and processing these actions.

DATES: This interim final rule is in effect July 19, 2021. Comments must be received by August 16, 2021.

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

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number or RIN for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at *http://www.regulations.gov* as they are received without change,

including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Melissa D. Walters, (703) 681–6027, *melissa.d.walters.civ@mail.mil.*

SUPPLEMENTARY INFORMATION:

I. Background

Signed into law on December 20, 2019, section 731 of the 2020 NDAA allows members of the uniformed services or their authorized representatives to file claims for personal injury or death caused by a DoD health care provider in certain military medical treatment facilities.

Historically, members of the armed forces have been unable to bring suit against the government under the *Feres* doctrine, named for the plaintiff in *Feres* v. *United States*. Based on this 1950 Supreme Court decision, active duty military personnel may not sue the government for personal injuries suffered incident to service (generally, while on active duty). The 2020 NDAA allows Service members, with certain limitations, to bring administrative claims to seek compensation for personal injury or death resulting from medical malpractice that occurred in certain military medical treatment facilities, in addition to compensation already received under the comprehensive compensation system that currently exists for military members and their families.

A substantiated claim under $100,000 will be paid directly to the member or his/her estate by DoD. The Treasury Department will review and pay claims that the Secretary of Defense values at more than $100,000. Service members must present a claim that is received by DoD within two years after the claim accrues. However, the statute allowed Service members to file claims in 2020 for injuries that occurred in 2017.

II. Legal Authority for This Rule

Based on section 731 of the NDAA, this rule adds to Title 32 of the Code of Federal Regulations a new part 45, Medical Malpractice Claims by Members of the Uniformed Services. Title 10 U.S.C. 2733a(f)(2)(A)(ii) describes the claims process, which includes: The claimant's submission of information to initiate a medical malpractice claim; the claimant's response to an adjudicator's request for new information required to substantiate the claim or to determine damages; an Initial Determination issued by DoD; the opportunity for a claimant to seek reconsideration of damage calculations in the case of clear error; and, in most cases, the opportunity for a claimant to file an administrative appeal.

Claims will be adjudicated based on uniform national standards consistent with generally accepted standards used in a majority of States in adjudicating claims under the Federal Tort Claims Act (FTCA), 28 U.S.C. 2671 *et seq.,* without regard to the place where the Service member received medical care.

III. Summary of Provisions Contained in This Rule

This rule discusses who may file a claim (generally, a member of a uniformed service allegedly harmed incident to service by malpractice); what DoD health care providers may be involved (DoD personnel and personal services contractors acting within the scope of their employment or duties; where the malpractice must have occurred (in a ''military medical treatment facility'' (MTF) (10 U.S.C. 1073d); how to file (a written request mailed to a Military Department-specific address); records DoD will consider (submissions presented by claimant and any available relevant government records and information otherwise available to DoD); who has the burden of proof (claimant must substantiate the claim); how to substantiate a claim; deciding what caused the alleged harm (DoD liability proportionate to harm attributable to DoD health care providers); use of final DoD or VA disability determinations if applicable; calculating economic damages (principally actual and future health care costs, costs associated with long term care and disability, and loss of future earnings); determining non-economic damages (including pain and suffering, up to a capped amount); and initial decision and administrative appeal procedures (a single DoD appeals board decides appeals on the written record as a whole). More detailed information is below.

Section 45.1 Purpose

Section 45.1 explains the purpose of this part. It establishes the administrative process for adjudication of claims under the new 10 U.S.C. 2733a, which was added to 10 U.S.C. by section 731 of the National Defense Authorization Act for Fiscal Year 2020. The current comprehensive compensation system that currently exists for military members and their families, when members are injured or die incident to service, applies to all causes of death or disability, whether due to combat injuries, training mishaps, motor vehicle accidents, naturally occurring illnesses, with limited exceptions (*e.g.,* when the member is absent without leave or the injury is due to the member's intentional misconduct or willful negligence). The new law provides for the possibility of additional compensation beyond that provided by this comprehensive compensation system for personal injury or death of a military member caused by medical malpractice by a DoD health care provider in certain circumstances.

Section 45.1 also notes that the new medical malpractice claims process is separate from the Military Health System Healthcare Resolutions Program.[1] This existing program is an independent, neutral, and confidential system that promotes full disclosure of factual clinical information involving adverse events and outcomes, and mediation of clinical conflicts. The program is part of the Military Health System's commitment to transparency, which also includes a patient's right to be heard as part of any quality assurance review. To the extent a military member (or any other health care beneficiary) seeks to obtain more information about an adverse clinical event, the Healthcare Resolutions Program continues to be a valuable resource independent of any legal process or claims system. However, the Healthcare Resolutions Program is not involved with claims or legal matters. Thus, when a patient files a malpractice claim, under § 45.1 Healthcare Resolutions Specialists disengage from further patient communications related to the events associated with the claim.

Section 45.2 Claims Payable and Not Payable in General

Section 45.2 provides some of the terms rendering claims payable and not payable. This section also covers the time for filing claims, generally within two years after the claim accrues. For claims filed in calendar year 2020, the time for filing was expanded to three years. Because 10 U.S.C. 2733a(b)(4) prescribes the time period for filing claims, state statutes of limitation or repose are inapplicable. Consistent with 10 U.S.C. 2733a(g), there is a limitation on the amount of attorney's fees or expenses. The adjudication of claims under this authority is not an adversarial proceeding, there is no prevailing party to be awarded costs, and there is no judicial review. The settlement and adjudication of medical malpractice claims of members of the uniformed services is final and conclusive per 10 U.S.C. 2735.

[1] *https://health.mil/Reference-Center/Policies/2019/06/18/Healthcare-Resolutions-Disclosure-Clinical-Conflict-Management-and-HCP.*

A claim under this regulation is payable only if it may not be settled or paid under any other law, including the FTCA per Title 10 U.S.C. 2733a(b)(5). Claims are adjudicated based on generally accepted standards used in a majority of States in adjudicating claims under the FTCA without regard to the place where the service member received medical care per Title 10 U.S.C. 2733a(f)(2)(B). In adjudicating claims, DoD will make every effort to determine the applicable law adopted by the majority of States (at least 26 States).

Certain exclusions that are part of FTCA law apply to claims under this new authority as well. These exclusions include the discretionary function exception, which generally bars any claim challenging a discretionary agency policy. Another FTCA exclusion that is applicable to claims under this part is the combatant activities exception, although only in extremely unusual circumstances such as an attack on a military hospital. It should be noted, however, that the FTCA exception regarding any claim arising in a foreign country is not applicable to claims under this part. Title 10 U.S.C. 2733a(f)(2)(B) refers to such claims as covered by the new authority.

Section 45.3 Authorized Claimants

Section 45.3 discusses who may file a medical malpractice claim. As provided in the statute, the claim must be filed by the member of the uniformed services who is the subject of the medical malpractice claim, or by an authorized representative on behalf of a member who is deceased or otherwise unable to file the claim due to incapacitation per Title 10 U.S.C. 2733a(b)(1). A claim may be filed by or on behalf of a reserve component member if the claim is in connection with personal injury or death occurring while the member was in a Federal duty status. 10 U.S.C. 2733a(i)(3). The statute only authorizes claims by members of the uniformed services. Thus, the regulation does not permit derivative claims or other claims from third parties alleging a separate injury as a result of harm to a member of the uniformed services. Additionally, medical malpractice claims from members must be for an injury incident to service per 10 U.S.C. 2733a(a). For members on active duty, almost any injury or illness arising out of medical care received at a MTF by a DoD health care provider is considered incident to service. Medical care provided to a service member based on military status is incident to service.

Section 45.4 Filing a Claim

Rules for filing a claim are addressed in § 45.4. A member of a uniformed service or, when applicable, an authorized representative, may file a claim. Any written claim will suffice provided that it includes the following: (a) The factual basis for the claim, which identifies the conduct allegedly constituting malpractice (*e.g.,* theory of liability and/or breach of the applicable standard of care); (b) a demand for a specified dollar amount; (c) signed by the claimant or claimant's duly authorized agent or legal representative; (d) if the claim is filed by an attorney, an affidavit from the claimant affirming the attorney's authority to file the claim on behalf of the claimant; (e) if the claim is filed by an authorized representative, an affidavit from the representative affirming his/her authority to file on behalf of the claimant; and (f) unless the alleged medical malpractice is within the general knowledge and experience of ordinary laypersons, an affidavit from the claimant affirming that the claimant consulted with a health care professional who opined that a DoD health care provider breached the standard of care that caused the alleged harm. Alternatively, if the claimant is represented by an attorney, unless the alleged medical malpractice is within the general knowledge and experience of ordinary laypersons, the claim must include an affidavit from the attorney affirming that the attorney consulted with a health care professional who opined that a DoD healthcare provider breached the standard of care that caused the alleged harm. This requirement for an affidavit at the time of filing the claim is consistent with the practice in a majority of States to require an expert report, expert affidavit, certification or affidavit of merit, or a similar requirement.

While DoD is not requiring an expert opinion at the time of filing a claim, claimants may submit whatever information and documentation they believe necessary to support their claim, as claimants have the burden to substantiate their claims. As part of the investigation and evaluation of a claim, DoD will access pertinent DoD or other available government information systems and records regarding the member in order to consider fully all facts relevant to the claim. This may include information in personnel records, medical records, the Defense Eligibility and Enrollment System (DEERS), reports of investigation, medical quality assurance records, and other information. Upon DoD's request, a claimant must identify any pertinent health care providers outside of DoD and provide a copy of his or her medical records from each of the identified health care providers, including a statement that the records are complete. A claimant must provide a medical release or medical releases upon DoD's request, enabling DoD to obtain medical records from the identified health care providers.

DoD may require that the claimant provide additional information DoD believes is necessary for adjudication of the claim, including the submission of an expert opinion at the claimant's expense. If DoD intends to deny a claim in which an expert opinion has not been submitted, prior to denying the claim, DoD will notify the claimant and provide the opportunity for submission of an expert opinion at the claimant's expense. DoD may determine an expert opinion is not required when allegations of medical malpractice are within the general knowledge and experience of ordinary laypersons, such as when a foreign object is improperly left in the body or an operation occurred on the wrong body part.

There is no discovery process for adjudication of claims. However, claimants may obtain copies of records in DoD's possession that are part of their personnel and medical records in accordance with DoD Instruction 5400.11, ''DoD Privacy and Civil Liberties Programs''; [2] and DoD Instruction 6025.18, ''Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs.'' [3] Claimants are not entitled to attorney work product, attorney client privileged communications, material that are medical quality assurance records protected under 10 U.S.C. 1102, predecisional material, or other privileged information.

Section 45.5 Elements of a Payable Claim; Facilities and Providers

Section 45.5 covers one of the statutory elements of payable claims, stating that the health care involved occurred in a covered military medical treatment facility by a DoD health care provider acting within the scope of employment. As stated in the statute, the claimed act or omission constituting medical malpractice must have occurred in a DoD medical center, inpatient hospital, or ambulatory care center. A

[2] Available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/540011p.pdf?ver=gM7QU0FeRs8wMwzFXS8uSA%3d%3d.*

[3] Available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602518p.pdf?ver=2019-03-13-125803-017.*

claim may not be based on health care services provided by DoD health care providers in any other locations, such as in the field, battalion aid stations, ships, planes, deployed settings, or any other place that is not a covered MTF. With respect to covered DoD health care providers, they include members of the uniformed services, DoD civilian employees, and personal services contractors of the Department authorized by DoD to render health care services. A non-personal services contractor or a volunteer working in an MTF is not a DoD health care provider for purposes of a payable claim. Claims filed in court against non-personal services contractors and volunteers would be analyzed under the *Feres* doctrine. The DoD health care provider must be acting within the scope of employment, meaning that the provider was acting in furtherance of his or her duties in the MTF. For personal services contractors, ''scope of employment'' means the contractor was acting within the scope of his or her duties.

Section 45.6 Element of Payable Claim: Negligent or Wrongful Act or Omission

Section 45.6 establishes rules for determining if a provider's act or omission was negligent or wrongful. In general, a claimant needs to prove by a preponderance of evidence that a DoD health care provider in a covered MTF acting within the scope of employment had a professional duty to the patient involved and by act or omission breached that duty in a manner that proximately caused the harm. The provider must exercise the same degree of skill, care, and knowledge ordinarily expected of providers in the same field or specialty in a comparable clinical setting. The standard of care is determined based on generally recognized national standards, not on the standards of a particular region, State or locality. A claimant may present evidence to support what the claimant believes is the standard of care. A claimant may present evidence to support the failure of the DoD health care provider to meet the standard of care based on the medical records of the patient and other documentary evidence of the acts or omissions of the health care provider.

In addition to the information submitted by the claimant, DoD may consider all relevant information in DoD records and information systems or otherwise available to DoD, to include information prepared by or on behalf of DoD in connection with adjudication of the claim. DoD will consider medical quality assurance records relevant to the health care provided to the patient. As required by 10 U.S.C. 1102, DoD medical quality assurance records are confidential. While such records may be used by DoD, any information contained in or derived from such records may not be disclosed to the claimant.

Section 45.7 Element of Payable Claim: Proximate Cause

Rules on determining whether the alleged malpractice was the proximate cause of the harm suffered by the member are the subject of § 45.7. In general, a claimant must prove by a preponderance of evidence that a negligent or wrongful act or omission by a DoD health care provider was the proximate cause of the harm suffered by the member. DoD is liable for only the portion of harm that is attributable to the medical malpractice of a DoD health care provider per 10 U.S.C. 2733a(c)(1). To the extent other causes contributed to the personal injury or death of the member, whether pre-existing, concurrent, or subsequent, the potential amount of compensation under this regulation will be reduced by that proportion of the alternative cause(s); however, if the claimant's own negligence constituted more than 50% of the fault, the claim is not payable.

Section 45.8 Calculation of Damages: Disability Rating

Section 45.8 provides rules related to disability ratings and adjudication of these ratings under disability evaluation systems. DoD will use the disability rating established in the DoD Disability Evaluation System under DoD Instruction 1332.18 [4] or otherwise established by the Department of Veterans Affairs (VA) to assess the extent of the harm alleged to have been caused by medical malpractice. A VASRD-based disability percentage represents the Government's estimate of the lost earning capacity attributable to an illness or injury incurred during military service.

Section 45.9 Calculation of Damages: Economic Damages

Calculation of economic damages, which are one component of a potential damages award, is the subject of § 45.9. Elements of economic damages in personal injury claims are past expenses, including medical, hospital and related expenses actually incurred, and future medical expenses. Also covered are lost earnings, loss of earning capacity, and compensation paid to a person for essential household services and activities of daily living that the member can no longer provide for himself or herself.

Section 45.10 Calculation of Damages: Non-Economic Damages

Non-economic damages are also covered as outlined in § 45.10. Elements of non-economic damages in medical malpractice cases consist of past and future conscious pain and suffering, physical disfigurement, and loss of enjoyment of life. Consistent with the rule of law in a majority of States, total non-economic damages may not exceed a cap amount. Based on the current average cap amount in those States, the total cap amount for all non-economic damages arising from the malpractice is set at $500,000.

Section 45.11 Calculation of Damages: Offsets for DoD and VA Compensation

Section 45.11 provides that in the calculation of damages there is a deduction for compensation paid or expected to be paid by DoD or VA to the service member for the same harm that is caused by the medical malpractice. Tort damage awards against the U.S. are generally offset by other compensation paid by the U.S. for the same harm that is the subject of a malpractice claim so that the U.S. does not pay more than once for the injury.

This section lists categories of compensation that are included as offsets to potential malpractice damages awards when that compensation relates to harm caused by the act or omission involved, including: Pay and allowances while a member remains on active duty or in an active status; disability retired pay; disability severance pay; incapacitation pay; involuntary and voluntary separation pays and incentives; death gratuity; housing allowance continuation; Survivor Benefit Plan; VA disability compensation; VA Dependency and Indemnity Compensation; Special Survivor Indemnity Allowance; Special Compensation for Assistance with Activities of Daily Living; Program of Comprehensive Assistance for Family Caregivers; and the Fry Scholarship. Also included is an offset of the value of TRICARE coverage, including TRICARE-for-Life for a disability retiree, family, or survivors. Future TRICARE coverage is a major part of the Government's compensation package for a disability retiree or survivor. Potential malpractice awards are not offset by the present value of some payments and benefits for which Service members have made payments or contributions, which would be difficult to quantify,

[4] Available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133218p.pdf?ver=2018-05-24-133105-050.*

including Servicemembers Group Life Insurance; Traumatic Servicemembers Group Life Insurance; Social Security disability benefits; Social Security survivor benefits; prior Government contributions to a Thrift Savings Plan that are inherited by a beneficiary; and commissary, exchange, and morale, welfare, and recreation facility access; the value of legal assistance and other services provided by DoD. Medical care provided while in active service or in an active status prior to death, retirement, or separation is also not offset.

To illustrate what benefits are available under the existing comprehensive compensation system, both those that are offset and those that are not, and the value of these benefits, tables below in the section titled, ''Impact to the Government,'' provide notional examples of benefits available under the existing comprehensive compensation system during Fiscal Year 2020.

DoD will estimate the present value of future payments and benefits. Many of such payments and benefits in cases of death and disability are lifetime benefits for members or survivors. With respect to future compensation and benefits that would change if a surviving spouse remarries, DoD will not assume remarriage.

Section 45.12 Initial and Final Determinations

Section 45.12 provides rules for provision to claimants of an Initial Determination regarding the claim. The Initial Determination may take the form of a grant of a claim and an offer of settlement or denial of the claim.

If a claim does not contain the information required by § 45.4(b), DoD will issue an Initial Determination stating that DoD will issue a Final Determination denying the claim unless the deficiency is cured. DoD will provide the claimant 30 calendar days following receipt of the Initial Determination to cure the deficiency, unless an extension of time is granted for good cause. If the claimant does not timely cure the deficiency, DoD will issue a Final Determination denying the claim for failure to cure the deficiency. A Final Determination issued under § 45.12(a) may not be appealed.

If a claim does not, based upon the information provided, state a claim cognizable under 10 U.S.C. 2733a or this interim final rule, DoD will issue an Initial Determination denying the claim. An Initial Determination on these grounds may be appealed under the procedures in § 45.13.

If the claimant initially does not submit an expert report in support of his or her claim, where applicable, and DoD intends to deny the claim, DoD will issue an Initial Determination stating, without more, that DoD will issue a Final Determination denying the claim in the absence of an expert report. DoD will provide the claimant 90 calendar days following receipt of the Initial Determination to submit an expert report, unless an extension of time is granted for good cause. If the claimant does not timely submit an expert report, DoD will issue a Final Determination denying the claim, which may not be appealed, and will provide a brief explanation of the basis for the denial of the claim to the extent practicable.

Except as provided above, DoD will endeavor to provide a brief explanation of the basis for an Initial Determination to the extent practicable. However, as required by 10 U.S.C. 1102, medical quality assurance records may not be disclosed to anyone outside DoD, to include the claimant, other Federal agencies, or the judiciary. This prohibition applies to any information derived from a peer review obtained under DoD's Clinical Quality Management (CQM) Program to assess the quality of medical care provided by a DoD health care provider. DoD has a very extensive CQM Program (under DoD Instruction 6025.13 [5] and Defense Health Agency Procedural Manual 6025.13) [6] to assess the quality of health care services, identify areas where improvements can be made, and ensure appropriate accountability. The CQM Program includes a peer review of every potentially compensable event. DoD considers records of these reviews in determining whether there was a negligent or wrongful act or omission by a DoD health care provider in relation to the claim but may not lawfully disclose this information. Therefore, while DoD will attempt to explain the basis for the Initial Determination, DoD cannot disclose any information covered by 10 U.S.C. 1102.

The Initial Determination will include information on the claimant's right to file an administrative appeal. The claimant may request reconsideration of the damages contained in an Initial Determination if, within the time otherwise allowed to file an administrative appeal, the claimant identifies an alleged clear error in the damages calculation. DoD will review the alleged clear error and will issue an Initial Determination on Reconsideration either granting or denying reconsideration of the Initial Determination and adjusting the damages calculation, if appropriate. The Initial Determination on Reconsideration will include information on the claimant's right to appeal.

Section 45.13 Appeals

The issue of appeals from Initial Determinations is addressed in § 45.13. In any case, other than a claim that is denied for failure to provide an expert report, in which the claimant disagrees with the Initial Determination, the claimant has a right to file an administrative appeal. A claimant should explain why he or she disagrees with the Initial Determination but may not submit additional information in support of the claim unless requested to do so by DoD.

An appeal must be filed within 60 calendar days of the date of the Initial Determination, unless an extension of time is granted for good cause. If no timely appeal is filed, DoD will issue a Final Determination.

Under the new rule, appeals will be decided by an Appeals Board administratively supported by the Defense Health Agency. The Appeals Board will consist of not fewer than three and no more than five DoD officials designated by the Defense Health Agency from the Defense Health Agency and/or the Military Departments who are experienced in medical malpractice claims adjudication. Appeals Board members must not have had any previous role in the claims adjudication under appeal. Appeals are decided on the written record and decisions will be approved by a majority of the members. There is no adversarial proceeding and no hearing. The Appeals Board may obtain or request information or assessments from appropriate sources, including from the claimant, to assist in deciding appeals. The claimant has the burden of proof by a preponderance of evidence that the claim is substantiated in the written record considered as a whole. Every claimant will be provided a written Final Determination on the claimant's appeal, which may adopt by reference the Initial Determination or revise the Initial Determination, as appropriate. If the Final Determination revises the Initial Determination, DoD will provide a brief explanation of the basis for the revisions to the extent practicable. Appeals Board decisions are final and conclusive. The Appeals Board may reverse the Initial Determination to

[5] DoDI 6025.13, ''Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS),'' February 17, 2011; Incorporating Change 2 on April 1, 2020 (*whs.mil*).

[6] *https://health.mil/Reference-Center/Policies?query=6025.13&isDateRange=0&broadVector=000&newsVector=0000000&refVector=0000000001000000&refSrc=1.*

grant or deny a claim and may adjust the settlement amount contained in the Initial Determination either upwards or downwards, as appropriate.

Section 45.14 Final and Conclusive Resolution

Section 45.14 states that, as provided in the statute, the adjudication and settlement of a claim is final and conclusive. Unlike the FTCA, the Military Claims Act, 10 U.S.C. chapter 163, which provides the authority for this regulation, does not give Federal courts jurisdiction over claims. Thus, the administrative adjudication process for all claims under the Military Claims Act, including medical malpractice claims under this part, is final and not subject to judicial review in any court. No claim may be paid unless the amount tendered is accepted by the claimant in full satisfaction. Settlement agreements will incorporate the statutory requirements regarding limitations on attorneys' fees, as well as a bar to any other claim against the United States or DoD health care providers arising from the same set of facts.

Section 45.15 Other Claims Procedures and Administrative Matters

Finally, § 45.15 sets out other claims procedures and administrative matters.

If the claimant is represented by counsel, all communications will be through the claimant's counsel.

Laws applicable to false claims and false statements to the Government are applicable to claims and information relating to claims under this new authority.

This section also notes the requirement of 10 U.S.C. 2733a(e) that not later than 30 calendar days after a determination of medical malpractice or the payment of a claim, a report is sent to the Director, Defense Health Agency to be used for all necessary and appropriate purposes, including medical quality assurance. This means that DoD Final Determinations made under this new claims system—even if, due to offsets for compensation under the comprehensive system discussed above, no money is paid—will be reviewed under the Military Health System Clinical Quality Management Program, in accordance with DoD Instruction 6025.13 [7] and Defense Health Agency Procedural Manual 6025.13.[8] That program features comprehensive activities to monitor the quality of health care in MTFs, identify opportunities for improvement, and maintain appropriate accountability for health care providers. That system includes procedures to grant and take specified adverse actions on clinical privileges and report certain events to the National Practitioner Data Bank (NPDB) maintained by the Department of Health and Human Services as a data repository available to health care systems throughout the United States.[9] NPDB reporting includes cases where DoD compensation is paid through the Disability Evaluation System or survivor benefits attributable to medical malpractice by a DoD health care provider and now, under this part, paid malpractice claims. Reports to the NPDB are accompanied by reports to State licensing boards and certifying agencies of the health care providers involved. Therefore, in addition to providing an additional potential compensation remedy, 10 U.S.C. 2733a reinforces DoD Clinical Quality Management Program procedures for appropriate accountability of DoD health care providers.

IV. What To Expect in the Claims Process

a. Who may File a Claim. Service members or former/retired Service members (''you'') may file a claim. Your authorized representative may file a claim on your behalf if you are deceased or incapacitated. DoD will acknowledge receipt of your claim via mail and/or email using the contact information you provided in your claim.

b. What to Include with a Claim. Your claim must provide, in writing, the reason why you believe a DoD health care provider committed malpractice and the amount of money you believe you should receive. No specific form or format is required.

If you have an attorney, you need to include in your claim filing an affidavit confirming that you have authorized the attorney to represent you.

You usually will need to provide an affidavit with your claim filing that you consulted with a health care professional who opined that a DoD health care provider breached the medical standard of care and caused harm to you. You do not need to provide this affidavit if the malpractice is obvious, such as an operation on the wrong body part.

Because all claims differ, nothing else is required at the time you file your claim. DoD may find during the review of your claim that additional information is needed. DoD will ask you for this information at that time. You may, but are not required to, submit any other information that you believe supports your claim at the time you file it.

c. Where to File a Claim. You should submit the claim to your Military Department.

Army: Claims should be presented to the nearest Office of the Staff Judge Advocate, to the Center Judge Advocate of the Medical Center in question, or with US Army Claims Service, 4411 Llewellyn Avenue, Fort Meade, Maryland 20755, ATTN: Tort Claims Division.

Navy: Information, directions and forms for filing a claim may be found at *https://www.jag.navy.mil/.* Claims should be mailed to the Office of the Judge Advocate General, Tort Claims Unit, 9620 Maryland Avenue, Suite 205, Norfolk, Virginia 23511–2949.

Air Force: Claims should be presented either at the Office of the Staff Judge Advocate at the nearest Air Force Base, or sent by mail to AFLOA/JACC, 1500 W Perimeter Road, Suite 1700, Joint Base Andrews, MD 20762. POC: Medical Law Branch, AFLOA/JACC 240–612–4620 or DSN 612–4620.

d. Time for Filing a Claim. Generally, you must file your claim by the later of (1) two years from the date of the injury or death; or (2) the date you knew, or with the exercise of reasonable diligence should have known, of the injury or death and that the possible cause of the injury or death was malpractice. A special rule existed in 2020 that allowed claims from 2017 to be filed in 2020, but that rule has expired.

e. Initial Determination on Your Claim. Once you have filed your claim, DoD will locate medical records held by DoD and VA and review your claim to determine whether malpractice occurred.

DoD may ask you for additional information about your medical care as part of this review. If DoD concludes that medical malpractice occurred, DoD may ask you for information about the harm to you as a result of malpractice to determine the amount of money you will be offered as a settlement. This amount of money is also called ''damages.''

If DoD intends to deny your claim and you have not yet submitted an expert report in support of your claim, DoD will provide you with an opportunity to submit one before denying your claim. You usually will have 90 days to provide an expert report.

Once DoD has completed its review of your claim, you will be issued an Initial Determination. This Initial

[7] Available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602513p.pdf?ver=2019-03-11-081734-313.*

[8] Available at *https://health.mil/About-MHS/OASDHA/Defense-Health-Agency/Resources-and-Management/DHA-Publications.*

[9] Available at *https://www.npdb.hrsa.gov/.*

Determination will either state that your claim is granted and offer you an amount of money in settlement of your claim or will state that your claim is denied.

A settlement does not entitle you to any new benefits from DoD or the VA. A settlement will not cause you to lose any DoD or VA benefits, whether at the time of the settlement or in the future.

f. Reconsideration. If DoD has made a clear error in the calculation of the amount of money you are offered to settle your claim, you may request reconsideration. A clear error is an obvious or typographical error, such as a reference to $10 when it is clear $100 was intended. The reconsideration process was intended to fix minor issues without requiring you to file an appeal. You must file your request for reconsideration within 60 days of receipt of an Initial Determination. DoD will assume that you received the Initial Determination within five calendar days after the date the Initial Determination was mailed or emailed.

g. Appeals. If you disagree with an Initial Determination, you generally may file an administrative appeal. Your appeal should explain why you disagree with the Initial Determination. You must file your appeal within 60 days of receipt of an Initial Determination. DoD will assume that you received the Initial Determination within five calendar days after the date the Initial Determination was mailed or emailed.

You may not appeal a Final Determination issued because of deficiencies in your claim filing such as a missing affidavit or because DoD has determined you need to submit an expert report. You will have been given an opportunity to fix deficiencies or submit an expert report before the Final Determination is issued.

Your appeal will be decided by an Appeals Board of three to five DoD officials who have experience with medical malpractice claims and have no prior connection to your claim.

You may not submit additional information in support of your claim on appeal. DoD will ask you for additional information if it is needed.

The Appeals Board will issue a Final Determination on your claim. The Appeals Board may reverse the Initial Determination to grant or deny a claim. The Appeals Board may adjust the damages amount in the Initial Determination either upwards or downwards. A Final Determination is not subject to review in any court.

If you do not file an appeal, DoD will issue a Final Determination.

h. Settlement Agreement. You will be paid the damages amount offered in a Final Determination after you sign a settlement agreement provided to you by DoD.

i. Claims Process is Final. This claims process is the only process for Service members to bring medical malpractice claims related to their service. You may not challenge a Final Determination or the amount of any damages calculation contained in a Final Determination in court.

j. Attorneys. You may have an attorney assist you with your claim. If you have an attorney, DoD will communicate with your attorney instead of with you regarding your claim. Your attorney may not charge you attorney fees of more than 20 percent of the amount paid to you under this process.

V. Regulatory Analysis

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

Executive Orders 13556 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, distribution of impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Accordingly, this interim final rule has been reviewed by the Office of Management and Budget under the requirements of these Executive Orders. It has been determined to be a significant regulatory action, although not economically significant. Accordingly, this regulatory impact analysis presents the costs and benefits of the rulemaking.

b. Summary

This interim final rule implements requirements of the National Defense Authorization Act (NDAA) for Fiscal Year 2020 permitting members of the uniformed services or their authorized representatives to file claims for personal injury or death caused by a Department of Defense (DoD) health care providers in certain military medical treatment facilities. Because Federal courts do not have jurisdiction to consider these claims, DoD is issuing this rule to provide uniform standards and procedures for considering and processing these actions administratively.

c. Affected Population [10]

At the end of Fiscal Year 2019, there were approximately 1,400,000 Active Duty, 390,000 Reserve and National Guard, and 250,000 other uniformed Service members eligible for DoD healthcare benefits.[11] or around 19% of the total eligible beneficiary population. These uniformed Service members will be able to file claims with DoD alleging malpractice. There were approximately 8,140,000 other eligible beneficiaries to include retirees, retiree family members, and family members of Active Duty Service members. These other eligible beneficiaries currently may file claims with DoD alleging malpractice.

d. Costs

As a result of the rule, individuals who believe they were subjected to malpractice may consider filing a claim. In determining whether to file a claim, individuals may consult with medical professionals and attorneys and we assume that most claimants will have attorneys. We estimate that this will require 5 hours for individuals to locate an attorney, view and download pertinent medical records, and discuss the case with an attorney (or a medical professional for claimants without attorneys). At a mean hourly rate of $27.07 based on data from the Bureau of Labor Statistics (BLS),[12] the cost of this activity is $135.

The cost for a consultation with a medical professional, whether directly by the claimant or through an attorney varies by the type of professional. Based upon information available from consultations and reports obtained in malpractice claims against the government and estimates of time spent by DoD in similar activity when handling those claims, we estimate a typical review of records would take about 3 to 5 hours (and include reviewing journals in support of the professional's opinion), with an additional 2 to 4 hours to write a report (if such a report is submitted with a

[10] Data are from the ''Evaluation of the TRICARE Program: Fiscal Year 2020 Report to Congress—Access, Cost and Quality Data through Fiscal Year 2019.'' which can be found at *https://health.mil/Reference-Center/Reports/2020/06/29/Evaluation-of-the-TRICARE-Program-Fiscal-Year-2020-Report-to-Congress.*

[11] Active Duty include members of the Army, Navy, Air Force, Marines. The other uniformed services are the Coast Guard, Public Health Service, and the National Oceanic and Atmospheric Administration. The Space Force was established December 20, 2019, and was not included in this Fiscal Year 2019 data.

[12] According to the Bureau of Labor Statistics, the median weekly earnings for full-time wage and salary workers in 2020 was $984.00, for an hourly rate based on a 40-hour workweek of $24.60. See *https://www/bls.gov/cps/cpsaat39.htm.*

claim, which is not required). The Department will assume for purposes of this analysis that the same type of professional would be consulted as the professional against whom the malpractice is alleged (*e.g.,* a doctor providing an opinion about the standard of care if a doctor is alleged to have committed malpractice). Most medical malpractice claims are brought on a contingent fee basis [13] so there is no initial cost to the claimant. Based on similar claim analysis activity in handing malpractice claims, we estimate an attorney might spend 17–26 hours analyzing a claim before filing. We use BLS data [14] to value time spent by these individuals, and we adjust mean wage rates upward by 100 percent to account for overhead and benefits. This implies hourly rates of $206.12 for physicians, $76.94 for nurses, and $111.62 for physician assistants, and $143.18 for lawyers. As a result, the estimated cost for medical review would be approximately $231 to $1,855, and the estimated cost for attorney time would be approximately $2,434 to $3,723.

The cost to a Service member or an authorized representative for the filing itself will vary based on the amount of information the Service member includes with his or her filing. A basic letter stating the factual basis for the claim and including a demand for a specified dollar amount would cost the claimant postage ($0.55 per claim, or $27.50 for an estimated 50 claims) and possibly minimal photocopying. Claimants will likely choose to use certified mail, requiring additional postage of $3.35 per claim (or $167.50 for an estimated 50 claims per year). Two affidavits are likely required, one containing a statement from the claimant indicating he or she consulted with a health care professional and obtained an opinion from that health care professional that the medical standard of care was breached and one affirming that a representative is authorized to represent the claimant. Those entitled to legal assistance under 10 U.S.C. 1044 (such as Active Duty Service members, retired Service members, and survivors) would be able to obtain notarial services at no cost. Most likely, those filing claims would fall into one of these categories and so could obtain notarial services at no cost. However, this rule results in societal costs associated with these notarial services. We estimate that notarial services will require the equivalent of 20 minutes of paralegal time. Using BLS data,[15] and adjusting upward by 100 percent to account for overhead and benefits to arrive at an hourly rate of $54.44 implies $18.14 in costs per claim. Finally, although not required, a claimant could submit any other information he or she chooses, which would result in a variable cost. DoD assumes that pertinent medical records outside its system would be fairly recent could be accessed via web portals, resulting in a cost to the claimant of only the cost of printing and postage. If the claimant elects to submit receipts, the claimant would need to pay the cost of printing or photocopying, as well as postage. DoD requests public comment on costs faced by claimants.

In 2020, DoD received 149 malpractice claims filed by Active Duty beneficiaries under the process in this Part and 173 malpractice claims filed by other beneficiaries under either the FTCA or MCA. Section 2733a(b)(4) requires claims to be presented to DoD within two years after the claim accrues, although section 731 of the Fiscal Year 2020 NDAA allowed claims accruing in 2017 to be filed in 2020. In future years, when three years' worth of claim filings are not compressed in the same year and the requirement for consultation with a health care professional in certain circumstances in advance of filing takes effect, DoD would anticipate around 50 claims per year.[16] Based on information related to malpractice claims not filed after consideration, we estimate that 90% of the claims considered by individuals and their attorneys will not be filed.[17] As a result, we estimate that 500 claims will be considered, and that 50 claims will be filed by Service members per year.

The categories of costs for considered claims are described above. In sum, we estimate costs of $2,822 to $5,735 per claim. This implies total costs of $1,401,102 to $2,857,602 each year for considered claims.

Next, we estimate costs associated with processing claims. Many steps in processing a claim will be the same for DoD whether or not the claim has merit. Based on activity in non-medical malpractice claims, we anticipate 3 hours of paralegal time for activities such as logging in claims, sending acknowledgment letters, mailing certified letters containing the outcome of a claim, drafting vouchers for payment, and filing/data entry. Assuming a GS–11 paralegal at the step 5 salary rate of $81,634 based on the 2020 Washington, DC, locality pay table (an hourly rate of $39.12) and the total value of labor including wages, benefits, and overhead being equal to 200 percent of the wage rate, the cost for this paralegal activity per claim is $234.72. We estimate that the approximately same amount of time that a claimant's attorney would spend analyzing a claim (17–26 hours of attorney time) would be spent by DoD attorneys to analyze the claim, conduct legal research, consult with experts, and draft a determination. Assuming a GS 13/14 at an average GS 13/14 salary of $127,788 based on the 2020 Washington, DC, locality pay table (an hourly rate of $61.23) and the total value of labor including wages, benefits, and overhead being equal to 200 percent of the wage rate, this attorney activity would cost $2,081 to $3,184 per claim.

Of these 50 claims, for purposes of this analysis, based on historical malpractice claims data involving non-Service members, we assume 27% of claimants will have claims for which DoD determines malpractice occurred, or 14 claims. For these claims, based on time spent by DoD on the damages portion of current malpractice claims against the government, DoD estimates claimants' attorneys and DoD attorneys will spend 6–8 hours respectively on matters pertaining to damages. This results in a cost per claim of $859 to $1,145 for claimants' attorneys and $748 to $997 for DoD attorneys.

Of submitted claims, DoD estimates that claimants will appeal all claims that do not result in a payment of damages, resulting in 36 appeals annually. Note that this is described in more detail in the transfers section. We estimate it will take around the same amount of time spent on initial determination activities for appeal activities, or 17–26 hours per claim for both claimants' attorneys (at a cost of $2,434 to $3,723) and DoD attorneys (at a cost of $2,081 to $3,184) and 3 hours per claim by DoD paralegals (at a cost of $235). This implies total annual costs of $171,000 to $257,112 for appeals.

[13] Joanna Shepherd, Uncovering the Silent Victims of the American Medical Liability System, 67 Vanderbilt Law Review 151, 162 (2019) Available at: *https://scholarship.law.vanderbilt.edu/vlr/vol67/iss1/2.*

[14] See *https://www.bls.gov/oes/2020/may/oes_nat.htm.* Note that we use wages for family medical physicians as a proxy for physicians.

[15] See *https://www.bls.gov/oes/2020/may/oes_nat.htm.*

[16] These are the total number of claims, prior to any analysis of the merits of the claims, or analysis of whether the claims were properly filed (*e.g.,* whether the claims were timely). The Congressional Budget Office (CBO), when scoring section 731, assumed an additional 50 claims per year would be paid at cost of $600,000 per claim, for a total of $30,000,000 per year or $300,000,000 over 10 years. These estimates did not appear to take into account offsets so the number of paid claims will be less.

[17] Joanna Shepherd, Uncovering the Silent Victims of the American Medical Liability System, 67 Vanderbilt Law Review 151 (2019) Available at: *https://scholarship.law.vanderbilt.edu/vlr/vol67/iss1/2.*

As a result, we estimate total annual processing costs for these 50 claims to be $309,284 to $458,036.

In summary, total estimated annual costs of this interim final rule are $1,710,386 to $3,315,638.

e. Transfers

Regardless of the number of claims in which malpractice occurred, the only claims in which damages will be awarded are those which exceed the offsets for any payment to be made.[18] Subject to some exceptions such as insurance benefits for which Service members have paid premiums, benefits received through the DoD and VA comprehensive compensation system applicable to all injuries and deaths will be applied as an offset in calculating malpractice damages to prevent a double recovery. Because of these offsets, regardless of the number of claims filed, the only claims pertinent for purposes of payments made by the government are those that would exceed applicable offsets.

We estimate 7 claims per year will result in additional payments made to individuals, which is the number of claims anticipated to involve additional payments after offsets are applied. To help explain how we reached this estimate, we prepared the following tables as notional examples to illustrate what benefits are available under the existing comprehensive compensation system, both those that are offset and those that are not, and the value of these benefits in Fiscal Year 2020. In addition to the benefits in the above tables, disability retirees and survivors receive healthcare for life through TRICARE. In Fiscal Year 2020, based on information from the Office of the Assistant Secretary of Defense for Health Affairs, the average value of the TRICARE benefit for an under-65 retiree family of three was $14,600 per year. Benefits provided through the Social Security Administration, such as Social Security disability benefits and Social Security survivor benefits, are also in addition to the above tables. Calculations in the tables were provided by the Office of Military Compensation Policy, within the Office of the Under Secretary of Defense for Personnel and Readiness.

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[18] The Congressional Budget Office (CBO), when scoring section 731, assumed an additional 50 claims per year would be paid at cost of $600,000 per claim, for a total of $30,000,000 per year or $300,000,000 over 10 years. These estimates did not appear to take into account offsets so the number of paid claims will be less.

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Table 1: Notional Examples of Benefits Following a Service Member's Death on Active Duty – Fiscal Year 2021 Values

	Type of Payment	Description	(a) O-5[19] (16 Years of Service) Married (age 38) with Two Children	(b) E-6 (10 YOS) Married (age 29) with Two Children	(c) E-4 (3 Years of Service) Married (age 22) with One Child
			Amount	Amount	Amount
ONE-TIME PAYMENTS	**Service Members Group Life Insurance (SGLI)**	Life insurance. All members are automatically covered unless declining coverage. Amount shown assumes member elected maximum coverage. Payment is tax-free.	$400,000	$400,000	$400,000
	Death Gratuity	Immediate tax-free payment to eligible survivors of members who die while on active duty or certain inactive duties. Amount does not vary.	$100,000	$100,000	$100,000
	Total Immediate Payments		**$500,000**	**$500,000**	**$500,000**
RECURRING ANNUAL PAYMENTS	**Survivor Benefit Plan (SBP)**	Annuity paid to the surviving spouse for life, or until remarriage if surviving spouse remarries prior to age 57. This payment is offset by Dependency and Indemnity Compensation (DIC), if DIC is paid to the spouse.[20]	$41,304 ($25,013 after DIC offset)	$17,274 ($984 after DIC offset)	$10,679 (fully offset by DIC)
	Dependency and Indemnity	Tax-free monetary benefit paid to eligible survivors of military	$24,362.40	$24,362.40	$20,326.56

	Type of Payment	Description	(a) O-5[19] (16 Years of Service) Married (age 38) with Two Children	(b) E-6 (10 YOS) Married (age 29) with Two Children	(c) E-4 (3 Years of Service) Married (age 22) with One Child
			Amount	Amount	Amount
	Compensation (DIC)	members who died in the line of duty or eligible survivors of Veterans whose death resulted from a service-related injury or disease. Paid by Department of VA.[21]			
	Special Survivor Indemnity Allowance (SSIA)	Paid to the surviving spouse if the spouse is subject to an offset of SBP due to receipt of DIC.[22]	$3,924	$3,924	$3,924
	Total Annual Recurring Payment for First Year	SBP (decreased by the amount of DIC) + DIC + SSIA. Amount shown is in 2020 dollars.	$53,299	$29,270	$24,250
	Estimated Lifetime Sum of Annual Payments	Assumptions: • Spouse lives to age 87, but does not remarry prior to age 57. • SBP (offset by DIC) is paid to the spouse for life rather than to the children. • DIC for child ends 10 years after the death of the member when children reach age 19 (note: for the E-4, it assumes 15 years after death of the member) and resumes when the spouse reaches age 65. • Average annual cost of living adjustment is 2.75%.	$4,842,372	$3,151,453	$3,749,434

	Type of Payment	Description	(a) O-5[19] (16 Years of Service) Married (age 38) with Two Children	(b) E-6 (10 YOS) Married (age 29) with Two Children	(c) E-4 (3 Years of Service) Married (age 22) with One Child
			Amount	Amount	Amount
	Total Estimated Government-Provided Direct Benefits (Immediate + Recurring Payments)		**$5,342,372**	**$3,651,453**	**$4,249,434[23]**

Table 2: Notional Estimates of Monthly DoD and VA Disability Benefits for a Member Permanently Injured on Active Duty – Fiscal Year 2021 Values

Type of Payment	Description	(a) O-3 (Over 8) Age 30, Married Male with Two Children with 100% Disability	(b) E-6 (Over 8) Age 26, Married Female with Two Children with 100% Disability	(c) O-3 (Over 8), Age 30 Married Male with Two Children with 50% Disability	(d) E-6 (Over 8) Age 26, Married Female with Two Children with 50% Disability
		Monthly	*Monthly*	*Monthly*	*Monthly*
DoD Disability Retired Pay Calculated Based on Disability Percentage (Before VA Offset)	Disability retired pay under Chapter 61, Title 10, U.S.C., is determined by multiplying the disability percentage (maximum 75 percent) by the retired pay base, which is the average of the highest 36 months of pay that member (received.[24]	$4,542	$2,519	$3,028	$1,679
Retired Pay Calculated Based on Years of Service	*A disability retiree has the option of choosing to have retired pay calculated based on the disability percentage (A) or based on longevity of service (B). In most cases, the disability percentage results in a greater*	*$1,211*	*$671*	*$1,211*	*$671*

Type of Payment	**Description**	**(a) O-3 (Over 8) Age 30, Married Male with Two Children with 100% Disability**	**(b) E-6 (Over 8) Age 26, Married Female with Two Children with 100% Disability**	**(c) O-3 (Over 8), Age 30 Married Male with Two Children with 50% Disability**	**(d) E-6 (Over 8) Age 26, Married Female with Two Children with 50% Disability**
	amount of retired pay. Longevity retired pay is calculated by multiplying years of service by the average of the highest 36 months of pay by the applicable retirement program multiplier.[25]				
VA Disability Compensation	A tax-free monetary benefit paid to veterans with disabilities that are the result of a disease or injury incurred or aggravated during active military service. The benefit amount is graduated according to the degree of the disability on a scale from 10 percent to 100 percent (in increments of 10 percent).[26]	$3,492	$3,492	$1,086	$1,086
DoD Disability Retired Pay (After VA Offset)	A retiree must waive a portion of his or her gross DoD retired pay, dollar for dollar, by the amount of his or her VA Disability Compensation pay	$1,049	$0	$1,941	$592
Total Monthly DoD and VA Compensation	VA Disability Compensation + DoD Disability Retired Pay After VA Offset.	$4,541	$3,492	$3,027	$1,678
		Annual	*Annual*	*Annual*	*Annual*
Annual DoD and VA Compensation	Total Monthly DoD and VA Compensation x 12 months	**$54,492**	**$41,904**	**$36,324**	**$20,136**

Type of Payment	Description	(a) O-3 (Over 8) Age 30, Married Male with Two Children with 100% Disability	(b) E-6 (Over 8) Age 26, Married Female with Two Children with 100% Disability	(c) O-3 (Over 8), Age 30 Married Male with Two Children with 50% Disability	(d) E-6 (Over 8) Age 26, Married Female with Two Children with 50% Disability
Lifetime DoD and VA Compensation After Disability Retirement	Annual total multiplied by the number of years of projected life. The life expectation for a male 30-year-old retired officer is 54.5 additional years. The life expectation for a female 26-year-old retired enlisted member is 56.5 additional years. Amounts shown are in 2020 dollars without taking into account annual cost-of-living adjustments (COLA) (i.e., the present value). The current COLA estimate used by the DoD Board of Actuaries for calculating future military retired pay is 2.75 percent per year.	**$2,969,814**	**$2,367,576**	**$1,979,658**	**$1,137,684**

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We estimate that 7 claims per year would have damages that would exceed the offset amount of $1.1 million. We used the notional example in Table 2(d), the lowest of the estimates in the notional examples, as the basis for the $1.1 million offset. For the Table 2(b) example of the married enlisted member with two children in the grade of E–6 who is medically retired with a 50 percent disability rating, the current value of her lifetime compensation would be $1,142,430. In addition to the $1,142,430 paid, benefits include medical care for the retired Service member and her family. All these amounts would offset any damages award.

We then estimated the number of claims likely to exceed $1.1 million using claims data from non-Service member claims under the FTCA or MCA. In 2019 and 2020, the Military Departments had 14 claims from retirees or dependents under the FTCA or MCA with damages that exceeded $1.1 million, whether through settlement or an adverse court judgment. The average amount payable for these 14 claims over 2 years was approximately $2.7 million. In one year, therefore, we estimate that 7 claims by Service members would go forward that exceed the $1.1 million threshold for payable damages.

[19] In these tables, ''O–5'' refers to an officer grade; ''E–4'' to an enlisted grade.

[20] Amount shown is annual. The spouse SBP annuity is 55% of what retired pay would have been had the member retired with a full disability retirement on the date of his or her death. SBP is adjusted annually for cost-of-living. The amount reflected is for 2020 and assumes the spouse receives the full amount of SBP. SBP is subject to offset if the spouse also receives DIC (only for the portion of DIC payable to the spouse. If SBP is paid to the children instead of the spouse, there is no offset but the annuity ends when all children reach the age of majority).

[21] Basic Monthly Rate for 2020 is $1,340.14 plus $332.00 per child age 18 or younger. $16,081 is payable as DIC for the spouse which is offset against SBP.

[22] SSIA is only received if SBP is reduced by the amount of DIC. If children receive SBP in full while the spouse receives DIC, no SSIA is paid.

[23] The total payout for the spouse of the E–4 is higher than that for the E–6 because the spouse is 7 years younger, but both live until age 87.

[24] For simplicity of calculation, each member is assumed to have 12 months of service ''over 8 years'' and 24 months of service ''over 6 years'' in the same paygrade they currently hold, with a retirement date of December 31, 2019. Prior to retirement, each member was covered under the High-3 retirement program.

[25] For members who entered service prior to January 1, 2018, the applicable multiplier is 2.5 percent unless the member elected to opt into the Blended Retirement System or elected the Career Status Bonus and converted to the REDUX retirement program. For these examples, all members are assumed to have remained under the legacy ''High-3'' retirement program with a 2.5 percent multiplier.

[26] Rates for veteran + spouse + child + additional child at *https://www.benefits.va.gov/COMPENSATION/resources_comp01.asp#BM05*.

Assuming 7 claims per year going forward exceeding $1.1 million, and average damages of $1.6 million (the difference between the average amount of $2.7 million paid per claim in the non-Active Duty claims and the estimated $1.1 million in offsets per Service member claim), the additional payments made by the U.S. because of section 731are estimated to be $11.2 million per year. Of this, the first $100,000 for each claim would be paid by DoD and the remainder paid by the Treasury Department, for an estimated total of $0.7 million to be paid by DoD based on 7 claims and $1.05 million to be paid by the Treasury Department.

As the tables above illustrate, Government paid benefits would not be a factor, as this claims process would have no impact on what the benefits Service member is already receiving, has received, or is entitled to receive in the future based on his or her injuries.

Total transfers from the U.S. government to claimants are estimated to be $11.2 million per year.

f. Benefits

Absent the claims process established by section 731, Service members would not have the opportunity for potential monetary payments above the amounts they currently receive through current DoD and VA benefits. In addition to providing an additional potential compensation remedy, the claims process reinforces DoD Clinical Quality Management Program procedures for appropriate accountability of DoD health care providers. NPDB reporting includes cases where DoD compensation is paid through the Disability Evaluation System or survivor benefits attributable to medical malpractice by a DoD health care provider and now, under this part, paid malpractice claims. Reports to the NPDB are accompanied by reports to State licensing boards and certifying agencies of the health care providers involved. The claims process further provides an opportunity for DoD to identify opportunities for improvement in in the delivery of healthcare, potentially preventing harm to others based upon measures taken by DoD as a result of a claim even if the claim does not result in the payment of monetary damages. Finally, this process is only applicable in certain cases of medical malpractice.

g. Interim Final Rule Justification

This rule is being issued as an interim final rule based on explicit statutory authorization and clear Congressional intent. Specifically, 10 U.S.C. 2733a(f)(3) provides that in order ''to implement expeditiously'' the new law DoD may issue the regulations the statute requires ''by prescribing an interim final rule.'' The law also requires DoD to consider public comments and issue a final rule within one year after issuing an interim final rule. The new law became effective January 1, 2020, and Congress desired expeditious adjudication of claims arising from alleged instances of medical malpractice dating back to 2017. For this reason, there is good cause for finding, consistent with 5 U.S.C. 553(b)(B), that prior notice and public comment are impracticable, unnecessary, or contrary to the public interest.

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

This interim final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it is not a notice of proposed rulemaking under 5 U.S.C. 601(2).

i. Assistance for Small Entities

This interim final rule does not impose requirements on small entities.

j. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this interim final rule as not a major rule, as defined by 5 U.S.C. 804(2).

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

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require non-Federal spending in any one year of $100 million in 1995 dollars, updated annually for inflation. This interim final rule will not mandate any requirements for State, local, or tribal governments, nor affect private sector costs.

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

It has been determined that 32 CFR part 45 does not impose new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

m. Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This interim final rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 45

Medical, Malpractice, Claims, Uniformed Services.

■ Accordingly 32 CFR part 45 is added to read as follows:

PART 45—MEDICAL MALPRACTICE CLAIMS BY MEMBERS OF THE UNIFORMED SERVICES

Sec.

45.1 Purpose of this part.
45.2 Claims payable and not payable in general.
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45.5 Elements of payable claim: facilities and providers.
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45.11 Calculation of damages: offsets for DoD and VA Government compensation.
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45.13 Appeals.
45.14 Final and conclusive resolution.
45.15 Other claims procedures and administrative matters.

Authority: 10 U.S.C. 2733a.

§ 45.1 Purpose of this part.

(a) *In general.* The purpose of this part is to establish the rules and procedures for members of the uniformed services or their representatives to file claims for compensation for personal injury or death caused by the medical malpractice of a Department of Defense (DoD) health care provider. Claims under this part may be settled and paid by DoD under the Military Claims Act, Title 10, United States Code, Chapter 163, specifically section 2733a of Title 10 (hereinafter 10 U.S.C. 2733a, section 2733a, or the statute), as added to the Military Claims Act by section 731 of the National Defense Authorization Act for Fiscal Year 2020 (Pub. L. 116–92; 133 Stat. 1457). Claims are adjudicated under an administrative process. This administrative process follows a set of rules and procedures set forth in this part. These rules and procedures are based primarily on a number of detailed provisions in the statute.

(b) *Relationship to military and veterans' compensation programs.* Federal law provides a comprehensive system of compensation for military members and their families in cases of

death or disability incurred in military service. This system applies to all causes of death or disability incurred in service, whether due to combat injuries, training mishaps, motor vehicle accidents, naturally occurring illnesses, household events, with limited exceptions (*e.g.,* when the member is absent without leave or the injury is due to the member's intentional misconduct or willful negligence). This comprehensive compensation system applies to cases of personal injury or death caused by medical malpractice incurred in service as it does to all other causes. This part provides for the possibility of separate compensation in certain cases of medical malpractice but in no other type of case. A medical malpractice claim under this part will have no effect on any other compensation the member or family is entitled to under the comprehensive compensation system applicable to all members. However, a claimant under this part does not receive duplicate compensation for the same harm. Thus, with some limited exceptions, a potential malpractice damages award under this part is reduced or offset by the total value of the compensation the claimant is expected to receive under the comprehensive compensation system, whether or not the claimant ultimately receives such compensation, and the ultimate amount of a settlement under this part will be the amount, if any, that a potential malpractice damages award determined under the terms and conditions of this part exceeds the value of all the compensation and benefits the claimant is otherwise expected to receive from DoD or the Department of Veterans Affairs (VA).

(c) *Relationship to Healthcare Resolutions Program.* The medical malpractice claims process under this part is separate from the Military Health System Healthcare Resolutions Program. The Healthcare Resolutions Program, under Defense Health Agency Procedural Instruction 6025.17, is an independent, neutral, and confidential system that promotes full disclosure of factual information—including information involving adverse events and outcomes—and mediation of clinical conflicts. The program is part of the Military Health System's commitment to transparency, which also includes a patient's right to be heard as part of any quality assurance review of care provided. The Healthcare Resolutions Program is not involved in legal proceedings, compensation matters, or the adjudication of claims under this part. However, any member of the uniformed services may engage the Healthcare Resolutions Program to address non-monetary aspects of his or her belief that he or she has been harmed by medical malpractice by a DoD health care provider. Because it is not involved in claims or legal proceedings, the Healthcare Resolutions Program disengages when a claim is filed by a service member or his or her representative.

§ 45.2 Claims payable and not payable in general.

(a) *In general.* This section sets forth a number of terms and conditions included in the statute (10 U.S.C. 2733a) that describe claims that are payable and not payable. Some of these terms and conditions are discussed in more detail in later sections of this part.

(b) *Claim not otherwise payable.* As required by the statute (section 2733a(b)(5)), a claim under this Part may only be paid if it is not allowed to be settled and paid under any other provision of law. This limitation provides that it cannot be a claim allowed under the Federal Tort Claims Act (FTCA), 28 U.S.C. 1346 and Chapter 171. Claims against the United States filed by members of the uniformed services or their representatives for personal injury or death incident to service are not allowed under the FTCA. These claims may be allowed under this Part if they meet the other applicable terms and conditions.

(c) *Time period for filing claims.* (1) The statute (section 2733a(b)(4)) requires that a claim must be received by DoD in writing within two years after the claim accrues. For mailed claims, timeliness of receipt will be determined by the postmark.

(2) There is a special rule for claims filed during calendar year 2020. Such claims must be presented to DoD in writing within three years after the claim accrues. The tolling provisions under the Servicemembers Civil Relief Act, 50 U.S.C. 3901–4043, are not applicable under this section.

(3) For purposes of applying the time limit for filing a claim, a claim accrues as of the latter of:

(i) The date of the act or omission by a DoD health care provider that is the basis of the malpractice claim; or

(ii) The date on which the claimant knew, or with the exercise of reasonable diligence should have known, of the injury and that malpractice was its possible cause.

(4) State statutes of limitation or repose are inapplicable.

(d) *No claim for attorney's fees or expenses in addition to statutorily allowed amount.* In calculating the amount that may be paid under this part, consistent with section 2733a(c)(2), there is no additional amount permitted for attorneys' fees or expenses associated with filing a claim or participating in any process relating to the adjudication of the claim. The adjudication of claims under this part is not an adversarial proceeding and there is no prevailing party to be awarded costs.

(e) *Claims adjudication based on national standards.* As required by the statute (section 2733a(f)(2)(B)), claims are adjudicated based on national standards consistent with generally accepted standards used in a majority of States in adjudicating claims under the FTCA. The determination of the applicable law is without regard to the place of occurrence of the alleged medical malpractice giving rise to the claim or the military or executive department or service of the member of the uniformed services. Foreign law has no role in the case of claims arising in foreign countries. The legal standards set forth in other sections of this part apply to determinations with respect to:

(1) Whether an act or omission by a DoD health care provider in the context of performing medical, dental, or related health care functions was negligent or wrongful, considering the specific facts and circumstances;

(2) Whether the personal injury or death of the member was proximately caused by a negligent or wrongful act or omission of a DoD health care provider in the context of performing medical, dental, or related health care functions, considering the specific facts and circumstances;

(3) Requirements relating to proof of duty, breach of duty, and causation resulting in compensable injury or loss, subject to such exclusions as may be established by this Part; and

(4) Calculation of damages that may be paid.

(f) *Certain other claims not payable.* The generally accepted legal standards under FTCA that are required to be reflected in the adjudication of claims under this Part include certain exclusions that are part of FTCA law.

(1) The due care and discretionary function exceptions apply to claims under this part.

(i) The due care and discretionary function exceptions, 28 U.S.C. 2680(a), bar any claim based upon an act or omission of a DoD health care provider, exercising due care, in the execution of a statute or regulation or based upon the exercise or performance of any discretionary function or duty on the part of DoD or a DoD health care provider.

(ii) The due care exception applies to any DoD health care provider's act, if carried out with due care, or omission, if omitted with due care, in the execution of a statute or regulation. The due care exception applies whether or not the statute or regulation is valid.

(iii) The discretionary function exception applies to the exercise or performance or the failure to exercise or perform any discretionary function. The discretionary function exception applies whether or not the discretion involved was abused. It applies to any DoD health care provider's act or omission that is a permissible exercise of discretion under the applicable statutes, regulations, or directive and, by its nature, is susceptible to policy analysis. The discretionary function exception applies to DoD policy decisions regarding clinical practice, patient triage, force health protection, medical readiness, health promotion, disease prevention, medical screening, health assessment, resource management, hiring and retaining employees, selection of contractors, military standards, fitness for duty, duty limitations, and health information management, among other matters affecting or involving the provision of health care services.

(2) The quarantine exception applies to claims under this part. This exception, consistent with 28 U.S.C. 2680(f), bars any claim for damages caused by the imposition or establishment of a quarantine by any agency of the U.S. Government.

(3) The combatant activities exception applies to claims under this part. This exception, consistent with 28 U.S.C. 2680(j), bars any claim arising out of the combatant activities of the military or naval forces, or the Coast Guard, in time of war.

(4) The FTCA's exclusions under 28 U.S.C. 2674 of interest prior to judgment and punitive damages apply to any claim under this part.

(5) Claims based on intentional or negligent infliction of emotional distress, other intentional torts, wrongful death/life, strict liability, products liability, informed consent, negligent credentialing, or joint and severable liability theories are not payable under this part.

(6) Breach of medical confidentiality is not actionable under this part.

§ 45.3 Authorized claimants.

(a) *In general.* This section describes who may file a claim under this part. A claim may be filed only by a member of a uniformed service or an authorized representative on behalf of a member who is deceased or otherwise unable to file the claim due to incapacitation. A member of the uniformed services includes a cadet or midshipman from the military academies. It does not include an applicant to join a uniformed service or a delayed entry program recruit who has not been accessed into active duty.

(1) As provided in section 2733a(b)(1), the claim must be filed by the member of the uniformed services who is the subject of the medical malpractice claim or by an authorized representative on behalf of such member who is deceased or otherwise unable to file the claim due to incapacitation.

(2) In some circumstances, a claim otherwise payable under this part may be filed by or on behalf of a reserve component member. As provided in section 2733a(i)(3), those circumstances are that the claim is in connection with personal injury or death that occurred while the member was in a Federal duty status. This circumstance includes personal injury, death, or negligent diagnosis resulting from a negligent or wrongful act or omission that occurred while the member was in a Federal duty status. In the case of a member of the National Guard of the United States, a period of Federal duty status may be under Title 10, U.S. Code, or, based on 10 U.S.C. 12602, duty under title 32, U.S. Code. Other duty under State control is not covered.

(b) *Third party claims not allowed.* The statute only authorizes claims by members of the uniformed services. Thus, the regulation does not permit derivative claims or other claims from third parties alleging a separate injury as a result of harm to a member of the uniformed services. This prohibition includes claims by family members or survivors arising out of the circumstances of personal injury or death of a member.

(c) *Incident to service requirement.* Under section 2733a(a), the member's personal injury or death must be incident to service. An injury or death is incident to service if the medical care provided is based on the member's status under this section.

§ 45.4 Filing a claim.

(a) *In general.* A member of a uniformed service or, when applicable, an authorized representative may file a claim in writing. Any written claim will suffice as long as it is meets the requirements below and is signed by the claimant or authorized representative.

(b) *Contents of the claim.* The filed claim must include the following:

(1) The factual basis for the claim, including identification of the conduct allegedly constituting malpractice (*e.g.,* the theory of liability and/or breach of the applicable standard of care);

(2) A demand for a specified dollar amount;

(3) If the claim is filed by an attorney, an affidavit from the claimant affirming the attorney's authority to file the claim on behalf of the claimant;

(4) If the claim is filed by an authorized representative, an affidavit from the representative affirming his/her authority to file on behalf of the claimant;

(5) If the claimant is not represented by an attorney, unless the alleged medical malpractice is within the general knowledge and experience of ordinary laypersons, an affidavit from the claimant affirming that the claimant consulted with a health care professional who opined that a DoD health care provider breached the standard of care that caused the alleged harm. Alternatively, if the claimant is represented by an attorney, unless the alleged medical malpractice is within the general knowledge and experience of ordinary laypersons, the claimant must submit an affidavit from the attorney affirming that the attorney consulted with a health care professional who opined that a DoD health care provider breached the standard of care that caused the alleged harm. The requirement in this paragraph does not apply to claims filed prior to the publication of this Interim Final Rule.

(c) *Additional information to file in support of claim.* In the investigation and adjudication of a claim, DoD will access pertinent DoD records and information systems regarding the member in order to consider fully all facts that have a bearing on the claim. This collection may include information in personnel and medical records, the Defense Eligibility and Enrollment System (DEERS), reports of investigation, medical quality assurance records, and other information. Upon DoD's request, a claimant must identify any pertinent health care providers outside of DoD, and provide a copy of his or her medical records from each of the identified health care providers, including a statement that the records are complete. A claimant must provide medical release(s) upon DoD's request, enabling DoD to obtain medical records from these health care providers. Claimants may submit any other relevant information they believe supports their claim, such as information regarding the medical care involved, the acts or omissions the claimant believes constitute malpractice, medical opinions from

non-DoD providers, and evidence of pain and suffering or other harm.

(d) *Substantiating the claim.* Under section 2733a(b)(6), DoD is allowed to pay a claim only if it is substantiated. The claimant has the burden to substantiate the claim by a preponderance of the evidence. Upon receipt of a claim, DoD may require that the claimant provide additional information DoD believes is necessary for adjudication of the claim, including the submission of an expert opinion at the claimant's expense. DoD may determine an expert opinion is not necessary when negligence is within the general knowledge and experience of ordinary laypersons, such as when a foreign object is unintentionally left in the body or an operation occurred on the wrong body part.

(e) *No discovery.* There is no discovery process for adjudication of claims under this Part. However, claimants may obtain copies of records in DoD's possession that are part of their personnel and medical records in accordance with DoD Instruction 5400.11, ''DoD Privacy and Civil Liberties Programs''; DoD Instruction 6025.18, ''Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs,'' and supplemental DoD issuances to those Instructions. Claimants are not entitled to attorney work product, attorney client privileged communications, material that is part of a DoD Quality Assurance Program protected under 10 U.S.C. 1102, predecisional material, or other privileged information.

§ 45.5 Elements of payable claim: facilities and providers.

(a) *In general.* This section describes some of the necessary elements of a payable claim. The health care involved must occur in a covered military medical treatment facility (MTF) and be provided by a DoD health care provider acting within the scope of employment.

(b) *Covered MTF.* (1) As provided in section 2733a(b)(3) and (i)(1), the alleged act or omission constituting medical malpractice must have occurred in a covered MTF. For the purposes of this regulation, an MTF is a medical center, inpatient hospital, or ambulatory care center, as those facilities are described in 10 U.S.C. 1073d. Fixed dental clinics are also included.

(2) A claim may not be based on health care services provided by DoD health care providers in any other location, such as in the field, battalion aid stations, ships, planes, deployed settings, or in any other place that is not a covered MTF.

(c) *DoD health care provider.* As provided in section 2733a(i)(2), a DoD health care provider is a member of the uniformed services, DoD civilian employee, or personal services contractor of the Department (under 10 U.S.C. 1091) authorized by DoD to provide health care services. A non-personal services contractor or a volunteer working in an MTF is not a DoD health care provider for purposes of a payable claim under this part.

(d) *Scope of employment.* As provided in section 2733a(b)(2), for a claim to be payable under this part, the DoD health care provider whose negligent or wrongful act or omission is the basis of a claim must be acting within the scope of employment, meaning that the provider was acting in furtherance of his or her duties in the MTF. For personal services contractors, ''scope of employment'' means the contractor was acting within the scope of his or her duties.

§ 45.6 Element of payable claim: negligent or wrongful act or omission.

(a) *In general.* To establish the element of a negligent or wrongful act or omission, a member of a uniformed service (''claimant'') allegedly harmed incident to service by medical malpractice must prove by a preponderance of the evidence that one or more DoD health care providers in a covered MTF acting within the scope of employment had a professional duty to the patient involved and by act or omission breached that duty which proximately caused the injury or death.

(b) *Standard of care.* The professional duty referred to in paragraph (a) of this section is a duty to exercise the same degree of skill, care, and knowledge ordinarily expected of providers in the same field or specialty in a comparable clinical setting. The standard of care is determined based on generally recognized national standards, not on the standards of a particular region, State or locality. However, standard of care in the military context may be impacted by the particular setting and the availability of resources in that setting.

(c) *Breach of the standard of care.* A breach referred to in paragraph (a) occurs if the health care provider or providers by act or omission did not meet the standard of care.

(d) *Presenting evidence of the standard of care.* A claimant may present evidence to support what the claimant believes is the standard of care relevant to the care involved in the claim.

(e) *Presenting evidence of a failure to meet the standard of care.* (1) A claimant may present evidence to support what the claimant believes demonstrates the failure of one or more DoD health care providers to meet the standard of care. That evidence may be based on the medical records of the patient involved and other documentary evidence of the acts or omissions of health care providers involved, including expert reports.

(2) Evidence of an apology by a health care provider or any other DoD or Military Department personnel, such as hospital directors or commanders, to or regarding a patient will not be considered evidence of medical malpractice. Providers often apologize for unexpected or adverse outcomes independent of whether the provider's acts or omissions met the standard of care.

(f) *Information DoD will consider in assessing whether there was a negligent or wrongful act or omission.* (1) In addition to the information submitted by the claimant, DoD may consider all relevant information in DoD records and information systems or otherwise available to DoD, including information prepared by or on behalf of DoD in connection with adjudication of the claim.

(2) DoD will consider medical quality assurance records relevant to the health care provided to the patient. DoD's Clinical Quality Management Program features reviews of many circumstances of clinical care. Results of any such reviews of the care involved in the claim that occurred before or after the claim was filed may be considered by DoD in the adjudication of the claim. As required by 10 U.S.C. 1102, DoD medical quality assurance records are confidential. While such records may be used by DoD, any information contained in or derived from such records may not be disclosed to the claimant.

§ 45.7 Element of payable claim: proximate cause.

(a) *In general.* (1) In a case otherwise payable under this part, a claimant must prove by a preponderance of evidence that a negligent or wrongful act or omission by one or more DoD health care providers was the proximate cause of the harm suffered by the member.

(2) Under section 2733a(c)(1), DoD is liable for only the portion of compensable injury, loss, or damages attributable to the medical malpractice of a DoD health care provider. To the extent other causes contributed to the personal injury or death of the member, whether pre-existing, concurrent, or subsequent, the potential amount of compensation under this regulation will

be reduced by that proportion of the alternative cause(s).

(b) *Comparative negligence.* A rule of modified comparative negligence will apply to claims under this part. If a claimant was contributorily negligent in relation to the health care provided, damages will be reduced by the proportion of fault assigned to the Service member. If the claimant's own negligence constituted more than 50% of the fault, the claim is not payable.

(c) *Loss of chance or failure to diagnose.* A claimant may recover for loss of chance for a more favorable clinical outcome in the diagnosis and treatment of his or her illness or injury. The claimant must prove by a preponderance of the evidence that one or more DoD health care providers in a covered MTF acting within the scope of employment had a professional duty to the claimant and by act or omission breached that duty and proximately caused harm. In proving that the claimant suffered harm, the claimant must prove that the lost chance for a better outcome or the failure to diagnose a condition is attributable to the provider or providers. The claimant must prove a substantial loss as opposed to a theoretical or de minimis loss. The portion of harm attributable to the breach of duty will be the percentage of chance lost in proportion to the overall clinical outcome. Damages will be calculated based on this portion of harm.

(d) *Information DoD will consider in assessing proximate cause.* (1) In addition to the information submitted by the claimant, DoD may consider all relevant information in DoD records or information systems or otherwise available to DoD, including information prepared by or on behalf of DoD in connection with adjudication of the claim.

(2) DoD will consider medical quality assurance records relevant to the health care provided to the patient. DoD's Clinical Quality Management Program features reviews of many circumstances of clinical care. Results of any such reviews of the care involved in the claim that occurred before or after the claim was filed may be considered by DoD in the adjudication of the claim. As required by 10 U.S.C. 1102, DoD medical quality assurance records are confidential. While such records may be used by DoD, any information contained in or derived from such records may not be disclosed to the claimant.

§ 45.8 Calculation of damages: disability rating.

(a) *In general.* For certain purposes relating to calculating damages for a member in a claim under this part, DoD will use the disability rating established in the DoD Disability Evaluation System under DoD Instruction 1332.18 [1] or otherwise established by the Department of Veterans Affairs (VA) to assess the extent of the harm alleged to have been caused by medical malpractice. This rating is stated as a disability percentage under the VA Schedule for Rating Disabilities (VASRD) under 38 CFR part 4 or a successor provision. Under 10 U.S.C. 1216a, DoD is required to use the VASRD for assessing the degree of disability of a member under the Disability Evaluation System. DoD will use it for purposes of this part as well. A VASRD-based disability percentage represents the Government's estimate of the lost earning capacity attributable to an illness or injury incurred during military service. A Service member medically separated or retired through the Disability Evaluation System may receive distinct DoD and VA disability ratings. DoD will consider disability ratings, to the extent DoD deems pertinent, for other purposes relating to calculating damages, such as calculating loss of earning capacity and non-economic damages.

(b) *Disability rating procedures.* (1) If a claimant disagrees with the disability rating received in the DoD or VA disability evaluation or claims processes, the member must pursue the appeal opportunities available within the DoD and/or VA to change the member's disability rating.

(2) In any case in which a member has filed a claim under this part and also has a disability determination pending under DoD or VA disability evaluation or claims processes applicable to determinations or appeals, DoD may, in its discretion, hold in abeyance the claim under this part pending the outcome of the disability evaluation or claims process. DoD will notify the claimant that his or her claim is being held in abeyance.

(3) In any case in which a member has not yet received a DoD or VA disability evaluation because the member is retained on active duty, DoD will use the VASRD as the standard for assessing the degree of disability of the member relevant to the member's claim under this part.

§ 45.9 Calculation of damages: economic damages.

(a) *In general.* Economic damages are one component of a potential damages award. The claimant has the burden to prove the amount of economic damages by a preponderance of evidence. Estimates of future losses must be discounted to present value.

(b) *Elements of economic damages in personal injury cases.* Elements of economic damage are limited to the following:

(1) Past expenses, including medical, hospital, and related expenses actually incurred. These expenses do not include health care services provided or paid for by DoD or VA.

(2) Future medical, hospital, and related expenses. These expenses do not include health care goods and services for which the member is entitled to receive from, or be reimbursed for by, DoD (including TRICARE) or VA. Goods and services provided or paid for by DoD or VA are deemed sufficient to meet the claimant's needs for that particular type of good or service.

(3) Past lost earnings unrelated to compensation as a member of the uniformed services. Appropriate documentation is required.

(4) Loss of earning capacity, after deducting for the claimant's personal consumption from the date of injury causing death until expiration of the claimant's work-life expectancy, as substantiated by appropriate documentation. In addition, loss of retirement benefits is compensable and similarly discounted after appropriate deductions. Estimates must be discounted to present value.

(5) Compensation when the claimant can no longer perform essential household services on his or her own behalf, including activities of daily living. This compensation does not include goods and services the member is entitled to receive from, or be reimbursed for by, DoD or VA. Goods and services provided or paid for by DoD or VA are deemed sufficient to meet the claimant's needs for that particular type of good or service.

(c) *Information DoD will consider in calculating economic damages.* In addition to the information submitted by the claimant, DoD may consider all relevant information in DoD records or information systems or otherwise available to DoD, including assessments from appropriate documentary sources and experts available to DoD.

§ 45.10 Calculation of damages: non-economic damages.

(a) *In general.* Non-economic damages are one component of a potential damages award. The claimant has the burden of proof on the amount of non-economic damages by a preponderance of evidence.

[1] Available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133218p.pdf?ver=2018-05-24-133105-050.*

(b) *Elements of non-economic damages.* Elements of non-economic damage are limited to the following:

(1) *Past and future conscious pain and suffering by the claimant.* This element is physical discomfort as well as mental and emotional trauma or distress. Loss of enjoyment of life is compensable. The inability to perform daily activities that one performed prior to injury, such as recreational activities, is included in this element. DoD may request an interview of or statement from the member or other person with primary knowledge of the claimant.

(2) *Physical disfigurement.* This element is impairment resulting from an injury to a member that causes diminishment of beauty or symmetry of appearance rendering the member unsightly, misshapen, imperfect, or deformed. DoD may require a medical statement and photographs, documenting the claimant's condition.

(c) *Cap on non-economic damages.* In any claim under this part, total non-economic damages may not exceed a cap amount. The current cap amount is $500,000. Updates to cap amounts in subsequent years will be published periodically, consistent with changes in prevailing amounts in the majority of the States with non-economic damages caps.

(d) *Information DoD will consider in calculating non-economic damages.* In addition to the information submitted by the claimant, DoD may consider all relevant information in DoD records or otherwise available to DoD, including assessments from appropriate documentary sources and experts available to DoD.

§ 45.11 Calculation of damages: offsets for DoD and VA Government compensation.

(a) *In general.* Total potential damages calculated under this Part, both economic and non-economic, are reduced by offsetting most of the compensation otherwise provided or expected to be provided by DoD or VA for the same harm that is the subject of the medical malpractice claim. The general rule is that prospective medical malpractice damage awards are offset by DoD or VA payments and benefits that are primarily funded by Government appropriations. However, there is no offset for U.S. Government payments and benefits that are substantially funded by the military member.

(b) *Eligibility for payments and benefits.* In determining the offsets that are applied to a medical malpractice damages award under this part, DoD presumes that a claimant will receive all the payments and benefits for which the claimant is expected to be eligible, whether or not the claimant has taken steps to obtain the payment or benefit or ultimately receives such payment or benefit. A claimant may present evidence that he or she is not eligible for a payment or benefit to rebut the presumption.

(c) *Information considered.* In determining offsets under this section, DoD will consider all data available in DoD records or information systems, other U.S. Government records systems, and other information available to DoD. This data may include information on military pay and allowances, Disability Evaluation System outcomes, VA disability claims, marital status, number and ages of dependents, survivor benefits, and other information. Access to all such information will be in accordance with the Privacy Act, 5 U.S.C. 552a, and applicable implementing regulations.

(d) *Present value of future payments and benefits.* In determining offsets under this section, DoD will estimate the present value of future payments and benefits. Many such payments and benefits in cases of disability or death are lifetime benefits for members or survivors. With respect to any lifetime payments or benefits that may terminate upon the remarriage of a surviving spouse, DoD will not assume a remarriage. Estimates will be based on actuarial information provided by the Chief Actuary, DoD Office of the Actuary, taking into consideration methods and assumptions approved by the DoD Board of Actuaries and DoD Medicare-Eligible Retiree Health Care Board of Actuaries, respectively, as of the recent actuarial valuation date.

(e) *Payment and benefit programs.* The listings in this section of certain programs that offset and do not offset potential medical malpractice damages awards are not all-inclusive and are subject to adjustment as necessary to account for compensation otherwise provided by DoD or VA for the same harm that resulted from the medical malpractice. Because compensation programs are often changed by Congress, Federal agencies, or judicial decisions, DoD will annually review relevant programs and take account of any such changes for purposes of applying the rules of this section to the adjudication of claims under this part.

(f) *Payments and benefits that are offsets.* Potential damage awards under this part are offset by the present value of the following payments and benefits:

(1) Pay and allowances while a member remains on active duty or in an active status.

(2) Disability retired pay in the case of retirement due to the disability caused by the alleged medical malpractice.

(3) Disability severance pay in the case of non-retirement disability separation caused by the alleged medical malpractice.

(4) Incapacitation pay.

(5) Involuntary and voluntary separation pays and incentives.

(6) Death gratuity.

(7) Housing allowance continuation.

(8) Survivor Benefit Plan.

(9) VA disability compensation, to include Special Monthly Compensation, attributable to the disability resulting from the malpractice.

(10) VA Dependency and Indemnity Compensation, attributable to the disability resulting from the malpractice.

(11) Special Survivor Indemnity Allowance.

(12) Special Compensation for Assistance with Activities of Daily Living.

(13) Program of Comprehensive Assistance for Family Caregivers.

(14) Fry Scholarship.

(15) TRICARE coverage, including TRICARE-for-Life, for a disability retiree, family, or survivors. Future TRICARE coverage is part of the Government's compensation package for a disability retiree or survivor.

(g) *Payments and benefits that are not offsets.* Potential awards under this Part are not offset by the present value of the following payments and benefits.

(1) Servicemembers Group Life Insurance.

(2) Traumatic Servicemembers Group Life Insurance.

(3) Social Security disability benefits.

(4) Social Security survivor benefits.

(5) Prior Government contributions to a Thrift Savings Plan.

(5) Commissary, exchange, and morale, welfare, and recreation facility access.

(6) Value of legal assistance and other services provided by DoD.

(7) Medical care provided while in active service or in an active status prior to death, retirement, or separation.

§ 45.12 Initial and Final Determinations.

(a) *Denial of claim—deficient filing.* If a claim does not contain the information required by § 45.4(b), DoD will issue an Initial Determination stating that DoD will issue a Final Determination denying the claim unless the deficiency is cured.

(1) DoD will provide the claimant 30 calendar days following receipt of the Initial Determination to cure the deficiency, unless an extension of time is granted for good cause. The date of receipt of the Initial Determination will

be presumed to be five calendar days after the date the Initial Determination was mailed or emailed, unless there is evidence to the contrary.

(2) If the claimant does not timely cure the deficiency, DoD will issue a Final Determination denying the claim for failure to cure the deficiency. A Final Determination issued under paragraph (a) of this section may not be appealed.

(b) *Denial of claim—failure to state a claim.* If a claim does not, based upon the information provided, state a claim cognizable under 10 U.S.C. 2733a or this interim final rule, DoD will issue an Initial Determination denying the claim. Such an Initial Determination may be appealed under the procedures in § 45.13.

(c) *Denial of claim—absence of an expert report.* Where applicable, if the claimant initially does not submit an expert report in support of his or her claim and DoD intends to deny the claim, DoD will issue an Initial Determination stating, without more, that DoD will issue a Final Determination denying the claim in the absence of an expert report or manifest negligence.

(1) DoD will provide the claimant 90 calendar days following receipt of the Initial Determination to submit an expert report, unless an extension of time is granted for good cause. The date of receipt of the Initial Determination will be presumed to be five calendar days after the date the Initial Determination was mailed or emailed, unless there is evidence to the contrary.

(2) If the claimant does not timely submit an expert report, DoD will issue a Final Determination denying the claim and will provide a brief explanation of the basis for the denial to the extent practicable. A Final Determination issued under this paragraph (c) may not be appealed.

(d) *Initial Determination.* (1) Upon consideration of the information provided by the claimant and relevant information available to DoD, DoD will issue the claimant a written Initial Determination.

(2) The Initial Determination may be in the form of a certified letter and/or an email. The Initial Determination may take the form of a grant of a claim and an offer of a settlement or a denial of the claim. Subject to applicable confidentiality requirements, such as 10 U.S.C. 1102, privileged information, and paragraph (a) of this section, DoD will provide a brief explanation of the basis for the Initial Determination to the extent practicable.

(3) The Initial Determination will include information on the claimant's right to appeal if the claimant does not agree with the Initial Determination.

(4) The claimant may request reconsideration of the damages calculation contained in an Initial Determination if, within the time otherwise allowed to file an administrative appeal, the claimant identifies an alleged clear error—a definite and firm conviction that a mistake has been committed—in the damages calculation. DoD will review the alleged clear error and will issue an Initial Determination on Reconsideration either granting or denying reconsideration of the Initial Determination and adjusting the damages calculation, if appropriate. The Initial Determination on Reconsideration will include information on the claimant's right to appeal under the procedures in § 45.13.

§ 45.13 Appeals.

(a) *In general.* This section describes the appeals process applicable to Initial Determinations under this part, which include Initial Determinations on Reconsideration. With the exception of Initial Determinations issued under § 45.12(a), in any case in which the claimant disagrees with an Initial Determination, the claimant has a right to file an administrative appeal. The claimant should explain why he or she disagrees with the Initial Determination, but may not submit additional information in support of the claim unless requested to do so by DoD. An appeal must be received within 60 calendar days of the date of receipt by the claimant/counsel of the Initial Determination, unless an extension of time is granted for good cause. The date of receipt of the Initial Determination will be presumed to be five calendar days after the date the Initial Determination was mailed or emailed, unless there is evidence to the contrary. If no timely appeal is received, DoD will issue a Final Determination.

(b) *Appeals Board.* Appeals will be decided by an Appeals Board administratively supported by the Defense Health Agency. Although there may be, in DoD's discretion, multiple offices that initially adjudicate claims under this part (such as offices in the Military Departments), there is a single DoD Appeals Board. The Appeals Board will consist of not fewer than three and no more than five DoD officials designated by the Defense Health Agency from that agency and/or the Military Departments who are experienced in medical malpractice claims adjudication. Appeals Board members must not have had any previous role in the claims adjudication under appeal. Appeals are decided on a written record and decisions will be approved by a majority of the members. There is no adversarial proceeding and no hearing. There is no opposing party. The Appeals Board may obtain information or assessments from appropriate sources, including from the claimant, to assist in deciding the appeal. The Appeals Board is bound by the provisions of this Part and will not consider challenges to them.

(c) *Burden of proof.* The claimant on appeal has the burden of proof by a preponderance of evidence that the claim is substantiated in the written record considered as a whole.

(d) *Appeals Board decisions.* (1) Every claimant will be provided a written Final Determination on the claimant's appeal. The Final Determination may adopt by reference the Initial Determination or revise the Initial Determination, as appropriate. If the Final Determination revises the Initial Determination, DoD will provide a brief explanation of the basis for the revisions to the extent practicable.

(2) An Appeals Board decision is final and conclusive. 10 U.S.C. 2735.

(3) The Appeals Board may reverse the Initial Determination to grant or deny a claim and may adjust the settlement amount contained in the Initial Determination either upwards or downwards as appropriate.

§ 45.14 Final and conclusive resolution.

(a) *Administrative adjudication final.* As provided in 10 U.S.C. 2735, the adjudication and settlement of a claim under this part is final and conclusive and not subject to review in any court. Unlike the FTCA, the Military Claims Act, 10 U.S.C. chapter 163, which provides the authority for this part, does not give Federal courts jurisdiction over claims. Further, no claim under this Part may be paid unless the amount tendered is accepted by the claimant in full satisfaction.

(b) *Additional terms of settlement agreement.* (1) Settlement agreements under this part will incorporate the requirement of section 2733a(g)(1) that no attorney may charge, demand, receive, or collect for services rendered, fees in excess of 20 percent of any claim payment amount under this part.

(2) Because settlement and payment of a claim under this part is under section 2733a(b)(5) conditional on the claim not being allowed to be settled and paid under any other provision of law, a settlement agreement under this part will include a provision that it bars any other claim against the United States or DoD health care providers arising from the same set of facts.

§ 45.15 Other claims procedures and administrative matters.

(a) *Payment of damages.* In the event damages are awarded, the claimant or the claimant's estate is entitled to payment of those damages.

(b) *Communication through counsel.* If the claimant is represented by counsel, all communications will be through the claimant's counsel.

(c) *Remedies for filing false claims or making false statements.* Remedies available to the United States for filing false claims with Federal agencies or making false statements to Federal agencies and officials are applicable to claims and statements made in connection with claims under this part. Applicable authorities include 31 U.S.C. 3729 and 18 U.S.C. 1001. False claims and claims supported by false statements will be denied.

(d) *Reports to the Defense Health Agency.* As provided in section 2733a(e), not later than 30 calendar days after a Final Determination of medical malpractice or the payment of all or a portion of a claim under this part, a report documenting that determination is sent to the Director, Defense Health Agency to be used for all necessary and appropriate purposes, including those actions undertaken as part of DoD's Clinical Quality Management Program.

(e) *Monitoring claims adjudications under this part.* The General Counsel of the Defense Health Agency will monitor the performance of the claims adjudications structures and procedures under this part, including accounting for the number of claims processed under this part and the resolution of each claim and identifying means to enhance the effectiveness of the claims adjudication process.

(f) *Authority for actions under this part.* To ensure consistency and compliance with statutory requirements, supplementation of the procedures in this part is not permitted without approval in writing by the General Counsel of the Department of Defense. The General Counsel of the Department of Defense, under DoD Directive 5145.01, ''General Counsel of the Department of Defense,'' may delegate in writing authority for making Initial and Final Determinations, and other actions by DoD officials under this part. As used in this part, and at DoD's discretion, ''DoD'' may include, but is not limited to, Military Departments.

Dated: June 14, 2021.

Patricia L. Toppings,

OSD Federal Register Liaison, Department of Defense.

[FR Doc. 2021–12815 Filed 6–16–21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2021–0390]

Safety Zones; Annual Event in the Captain of the Port Buffalo Zone

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone located in Federal regulations for a recurring marine event. This action is necessary and intended for the safety of life and property on navigable waters during these events. During each enforcement period, no person or vessel may enter the respective safety zone without the permission of the Captain of the Port Buffalo.

DATES: The regulations in 33 CFR 165.939, Table 165.939, entry (a)(1), will be enforced from 9:45 p.m. to 11:15 p.m. on June 18, 2021.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR William Fitzgerald, Chief of Waterways Management, U.S. Coast Guard Marine Safety Unit Cleveland; telephone 216–937–0124, email *william.j.fitzgerald@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Safety Zones; Annual Events in the Captain of the Port Buffalo Zone listed in 33 CFR 165.939, Table 165.939, entry (a)(1), in Vermillion, OH, on all U.S. waters within a 420 foot radius of the fireworks launch site located at position 41°25′45″ N and 082°21′54″ W, (NAD 83) for the Festival of the Fish.

Pursuant to 33 CFR 165.23, entry into, transiting, or anchoring within the safety zone during an enforcement period is prohibited unless authorized by the Captain of the Port Buffalo or a designated representative. Those seeking permission to enter the safety zone may request permission from the Captain of Port Buffalo via channel 16, VHF–FM. Vessels and persons granted permission to enter the safety zone shall obey the directions of the Captain of the Port Buffalo or a designated representative. While within a safety zone, all vessels shall operate at the minimum speed necessary to maintain a safe course.

This notification of enforcement is issued under authority of 33 CFR 165.939 and 5 U.S.C. 552(a). In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port Buffalo determines that the safety zone need not be enforced for the full duration stated in this notification she may use a Broadcast Notice to Mariners to grant general permission to enter the respective safety zone.

Lexia M. Littlejohn,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. 2021–12840 Filed 6–16–21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0383]

RIN 1625–AA00

Safety Zone; M/V ZHEN HUA 26 Transit; Everport Container Terminal, San Pedro, California

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The U.S. Coast Guard is establishing a temporary moving safety zone around the M/V ZHEN HUA 26 while it transits through the navigation channel during its transit to Everport Container Terminal, Berth 227, in San Pedro, California. This safety zone is necessary to protect personnel, vessels, and the marine environment from hazards associated with the arms of three ship-to-shore gantry cranes which will extend more than 200 feet out from the transiting vessel when the arms are lowered, and from the vessel's stability condition due to an air draft greater than 300 feet when the cranes are in the up position. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port Los Angeles-Long Beach or a designated representative.

DATES: This rule is effective without actual notice from June 17, 2021, through 11:59 p.m. on June 21, 2021. For the purposes of enforcement, actual notice will be from 12:01 a.m. on June 11, 2021, until June 17, 2021.