

(5) For a culture-based test method, the volume of test material that results in a dilution of the product that is not bacteriostatic or fungistatic; and

(6) For a non-culture-based test method, the volume of test material that results in a dilution of the product that does not inhibit or otherwise hinder the detection of viable contaminating microorganisms.

(e) *Verification.* (1) For culture-based test methods, studies must be conducted to demonstrate that the performance of the test organisms and culture media are suitable to consistently detect the presence of viable contaminating microorganisms, including tests for each lot of culture media to verify its growth-promoting properties over the shelf-life of the media.

(2) For non-culture-based test methods, within the test itself, appropriate controls must be used to demonstrate the ability of the test method to continue to consistently detect the presence of viable contaminating microorganisms.

(f) *Repeat Test Procedures.* (1) If the initial test indicates the presence of microorganisms, the product does not comply with the sterility test requirements unless a thorough investigation by the quality control unit can ascribe definitively the microbial presence to a laboratory error or faulty materials used in conducting the sterility testing.

(2) If the investigation described in paragraph (f)(1) of this section finds that the initial test indicated the presence of microorganisms due to laboratory error or the use of faulty materials, a sterility test may be repeated one time. If no evidence of microorganisms is found in the repeat test, the product examined complies with the sterility test requirements. If evidence of microorganisms is found in the repeat test, the product examined does not comply with the sterility test requirements.

(3) If a repeat test is conducted, the same test method must be used for both the initial and repeat tests, and the repeat test must be conducted with comparable product that is reflective of the initial sample in terms of sample location and the stage in the manufacturing process from which it was obtained.

(g) *Records.* The records related to the test requirements of this section must be prepared and maintained as required by 21 CFR 211.167 and 211.194 of this chapter.

(h) *Exceptions.* Sterility testing must be performed on final container material or other appropriate material as defined in the approved biologics license

application or supplement and as described in this section, except as follows:

(1) Sterility testing is not required for Whole Blood, Cryoprecipitated Antihemophilic Factor, Platelets, Red Blood Cells, Plasma, Source Plasma, Smallpox Vaccine, Reagent Red Blood Cells, Anti-Human Globulin, and Blood Grouping Reagents.

(2) A manufacturer is not required to comply with the sterility test requirements if the Director of the Center for Biologics Evaluation and Research or the Director of the Center for Devices and Radiological Health, as appropriate, determines that data submitted in the biologics license application or supplement adequately establish that the route of administration, the method of preparation, or any other aspect of the product precludes or does not necessitate a sterility test to assure the safety, purity, and potency of the product.

PART 680—ADDITIONAL STANDARDS FOR MISCELLANEOUS PRODUCTS

5. The authority citation for 21 CFR part 680 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

6. Section 680.3 is amended by revising paragraph (c) to read as follows:

§ 680.3 Tests.

* * * * *

(c) *Sterility.* A sterility test shall be performed on each lot of each Allergenic Product as required by § 601.12 of this chapter.

Dated: June 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-15346 Filed 6-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF JUSTICE

28 CFR Part 104

[Docket No. CIV 151]

RIN 1105-AB39

James Zadroga 9/11 Health and Compensation Act of 2010

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: On January 2, 2011, President Obama signed into law the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act). Title II of the Zadroga Act reactivates the September

11th Victim Compensation Fund of 2001 and requires a Special Master, appointed by the Attorney General, to provide compensation to any individual (or a personal representative of a deceased individual) who suffered physical harm or was killed as a result of the terrorist-related aircraft crashes of September 11, 2001, or the debris removal efforts that took place in the immediate aftermath of those crashes. This rule proposes to amend the regulations implementing the Fund to reflect the changes made by the Zadroga Act.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before August 5, 2011. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (FDMS) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: Comments may be mailed to Kenneth L. Zwick, Director, Office of Management Programs, Civil Division, U.S. Department of Justice, Main Building, Room 3140, 950 Pennsylvania Avenue, NW., Washington, DC 20530. However, the Department encourages commenters to submit their comments using <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Kenneth L. Zwick, Director, Office of Management Programs, Civil Division, U.S. Department of Justice, Main Building, Room 3140, 950 Pennsylvania Avenue, NW., Washington, DC 20530, telephone 855-885-1555 (TTY 855-885-1558).

SUPPLEMENTARY INFORMATION:

Comment Period: The Department of Justice has allocated 45 days for public comment. This timeline is appropriate in light of the proposed regulations' substantial incorporation of the regulations that were previously used, the Department's experience in operating the Victim Compensation Fund, and the public interest in beginning operation of the Fund as soon as possible.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name and address) voluntarily submitted by the commenter.

You are not required to submit personal identifying information in order to comment on this rule. Nevertheless, if you want to submit personal identifying information (such

as your name and address) as part of your comment, but do not want it to be posted online, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You also must locate all the personal identifying information you do not want posted online in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You also must prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.regulations.gov>.

Personal identifying information and confidential business information identified and located as set forth above will be placed in the agency's public docket file, but not posted online. If you wish to inspect the agency's public docket file in person by appointment, please see the paragraph above entitled **FOR FURTHER INFORMATION CONTACT**.

Background

Pursuant to Title IV of Public Law 107-42 ("Air Transportation Safety and System Stabilization Act") (2001 Act), the September 11th Victim Compensation Fund of 2001 was open for claims from December 21, 2001, through December 22, 2003. The Fund provided compensation to eligible individuals who were physically injured as a result of the terrorist-related aircraft crashes of September 11, 2001, and to personal representatives of those who died as a result of the crashes.

Special Master Kenneth R. Feinberg was appointed by the Attorney General to administer the Fund. The Fund was governed by Interim Final Regulations issued on December 21, 2001, *see* 66 FR 66274, and by Final Regulations issued on March 13, 2002, *see* 67 FR 11233. During its two years of operation, the Fund distributed over \$7.049 billion to survivors of 2,880 persons killed in the September 11th attacks and to 2,680 individuals who were injured in the attacks or in the rescue efforts conducted thereafter. In 2004, Special Master Feinberg issued a report describing how the fund was administered. *See* Final Report of the Special Master for the September 11th Victim Compensation Fund of 2001,

available at http://www.justice.gov/final_report.pdf.

On January 2, 2011, President Obama signed the Zadroga Act into law. Title I of the Zadroga Act establishes a program within the Department of Health and Human Services to provide medical monitoring and treatment benefits to eligible individuals. Title II amends the 2001 Act and reopens the Fund. Among other changes, Title II adds new categories of beneficiaries for the Fund and sets new filing deadlines. It also imposes a cap on the total awards that can be paid by the Fund and limits the fees that an attorney may receive for awards made under the Fund.

The Zadroga Act, as originally enacted, did not appropriate administrative funds for the Fund to begin taking and processing claims. On April 15, 2011, President Obama signed into law Public Law 112-10, the continuing budget resolution for 2011, which permits the Fund to draw on the money originally allocated in the Zadroga Act in order to pay for its administrative expenses, beginning on October 1, 2011.

The Attorney General has appointed Sheila L. Birnbaum to serve as Special Master and to administer the Fund.

Statement From the Special Master

The James Zadroga 9/11 Health and Compensation Act of 2010 reopens the September 11th Victim Compensation Fund of 2001 to provide compensation to those who were physically injured or who died in the immediate aftermath of the terrorist attacks of September 11, 2001, including those who were injured during the clean-up and debris removal operations at a 9/11 crash site. This extension recognizes the considerable efforts of and effects on those engaged in or in the immediate vicinity of the response, recovery, and clean-up operations. The intent of the extension of the Fund is to provide fair and consistent compensation for those who are eligible and to do so in an efficient and timely manner.

As I stated when I was appointed, my goal is for the September 11th Victim Compensation Fund to be fair, transparent, and easy to navigate. In order to achieve that goal, I intend to build on the strong foundation that was established by Special Master Kenneth Feinberg in the first iteration of the Victim Compensation Fund and listen carefully to the views and concerns expressed by those who will be most affected by the program. I have sought to publish these proposed regulations quickly, so that there will be ample time for others to review them and for comments to be fully evaluated and the

regulations revised, where appropriate, before the Victim Compensation Fund opens later this year. Given the Victim Compensation Fund's success in its previous iteration, I propose to implement the original processes where I can and to propose additional or different procedures where the Zadroga Act requires a different approach.

At the outset, I would highlight some key principles that will guide my effort to create a process that is fair, transparent, and easy to navigate. First, I intend to make decisions based on the best scientific and medical evidence that is available. The Zadroga Act requires the Special Master to make a number of decisions about who is eligible to bring a claim, based on the nature of the individual's injuries, how it was caused, and whether the individual was present in an area where there was a demonstrable risk of physical harm resulting from the crashes. In order to make these determinations in a fair manner, I intend to look to the evidence that scientists and medical professionals rely on in exercising their best professional judgment. I also intend for the Victim Compensation Fund to keep pace with the evolving science and to ensure that as we learn more about conditions that may have been caused by the crashes or related debris-removal efforts, we are able to compensate claimants accordingly.

Second, Congress has appropriated a capped amount—\$2.775 billion payable over a period of years—for this program. Only \$875 million may be spent in the first five years of the program with the remainder being paid out in the sixth year. It is important therefore to assure that funds are targeted to the payment of eligible claims and to avoid procedures or guidelines that will dilute those payments. Funds used to process ineligible claims or for unnecessary administrative costs result in fewer funds available to pay intended and deserving claimants. In implementing the program, I intend to initiate procedures that will permit efficiency without sacrificing fairness, and to seek ways to minimize administrative expenses, thereby maximizing the amount available for distribution to eligible claimants.

Third, it is exceedingly important, in my view, to fully investigate the facts and circumstances surrounding the response, clean-up and debris removal activities necessitated by the attacks and the injuries that have resulted from these activities. To achieve these goals over the next several months, I will hold meetings with interested parties to explain the Victim Compensation Fund

and the proposed regulations, to hear your thoughts, and to answer as many questions as I can. I also look forward to reviewing your written comments about these proposed regulations, so that I can make the best decisions possible to refine the regulations and administer the program.

Discussion

The following discussion explains the proposed updates to the regulations governing the Fund. The proposed regulations are based on the Final Regulations governing the Fund from 2001–2004. Nevertheless, the Zadroga Act requires certain changes. Section I discusses proposed changes to the eligibility criteria; Section II discusses proposed procedures for amending claims; Section III discusses awards and proration of awards; and Section IV discusses proposed changes to the claims evaluation process. The text of the proposed regulations, as amended, is set forth following these explanatory sections. More detailed information, including a comparison of the original regulations to these proposed regulations, will be available on the Victim Compensation Fund's Web site at www.usdoj.gov/vcf.

I. Eligibility

Title II of the Zadroga Act sets criteria for determining whether a claimant is eligible to receive compensation from the Fund. The Act made changes to the criteria that governed eligibility in the Fund's previous iteration. In order to be eligible for the Fund, Title II of the Zadroga Act requires an individual to have been present at a "9/11 crash site" at the time or in the immediate aftermath of the crashes, and have suffered "physical harm or death as a result of" one of the air crashes or debris removal. In making these determinations, the Special Master is mindful that Congress has appropriated a limited amount of funds for paying awards, and therefore that inappropriate expansions of eligibility may result in lower awards for deserving claimants.

(a) *The Definition of "9/11 Crash Site"*

In requiring that a claimant have been present at a "9/11 crash site" in order to receive compensation from the Fund, Title II of the Zadroga Act recognizes that such sites include more than just the World Trade Center, Pentagon, and Shanksville, Pennsylvania sites and the buildings that were destroyed as a result. The Zadroga Act also encompasses two other areas.

(1) Sufficiently Close to the Site

First, Title II of the Zadroga Act defines "9/11 crash site" to include both the crash sites themselves and any area that is contiguous to one of the crash sites that the Special Master "determines was sufficiently close to the site that there was a demonstrable risk of physical harm resulting from" the impact of the aircraft or subsequent fire, explosions, or building collapses.

During the Fund's first iteration, Special Master Feinberg applied a regulation that required him to make this same determination. At that time, the most prevalent physical injuries were blunt trauma injuries suffered by those who were struck by debris or who were in the zone in which there was a demonstrable risk of physical harm from falling debris, explosions, or fire. Accordingly, the relevant area was defined to include the immediate area surrounding the World Trade Center: starting from the intersection of Reade and Center Streets, the northern boundary ran west along Reade Street to the Hudson River; the western boundary was the Hudson River; the southern boundary ran from the Hudson River, east along the line of W. Thames Street, Edgar Street and Exchange Place to Nassau Street; and the eastern boundary, starting from the intersection of Exchange Place and Nassau Street, ran north along Nassau Street to the intersection of Center and Reade Streets. See Final Report of the Special Master for the September 11th Victim Compensation Fund of 2001 at 19 and n. 53. The Zadroga Act, which covers conditions that may have been caused over longer periods of time and thus are not limited to harms caused by falling debris, states that the term "9/11 crash sites" "includ[es]" that original area but could also include other areas.

In determining which other areas to include, the Special Master will consider scientific evidence regarding the risks of physical harm resulting from the crashes and the text and structure of the Act, including the relationship between Title I and Title II and the goal of allocating the available funds to deserving claimants. Given these considerations, this proposed rule suggests that the term "9/11 crash site" includes the area in Manhattan south of the line that runs along Reade Street from the Hudson River to the intersection of Reade Street and Centre Street, south on Centre Street to the Brooklyn Bridge, and along the Brooklyn Bridge, or any other area contiguous to the crash sites that the Special Master determines was sufficiently close to the site that there

was a demonstrable risk of physical harm resulting from the impact of the aircraft or any subsequent fire, explosions, or building collapses (including the immediate area in which the impact occurred, fire occurred, portions of buildings fell, or debris fell upon and injured individuals). These proposed boundaries are substantially broader than those used in the Fund's first iteration and narrower than boundaries used for the World Trade Center (WTC) Health Program in Title I of the Act. The Special Master invites comments on the proposal.

(2) Routes of Debris Removal

Second, the Zadroga Act defines the term "9/11 crash site" to include "any area related to, or along, routes of debris removal, such as barges and Fresh Kills." The Special Master invites comments that provide information regarding the routes of debris removal.

(b) *Physical Harm or Death as a Result of the Crash or Debris Removal*

In requiring that a claimant have suffered "physical harm or death as a result of" one of the air crashes or the debris removal, the Zadroga Act also requires the Special Master to determine which physical harms and deaths were "a result of" the crashes or debris removal within the meaning of the statute. The Department notes that Title II of the Zadroga Act does not provide additional specificity about the harms that are to be covered by the Fund.

However, Title I of the Zadroga Act, which establishes the WTC Health Program, contains a list of illnesses and health conditions for which exposure to air borne toxins, other hazards and any other adverse conditions resulting from the September 11, 2001 terrorists attacks could be determined by experienced medical professionals to be substantially likely to have been a significant factor in aggravating, causing, contributing to illness or health condition, as well as procedures for adding additional conditions to the list over time. That title also provides that in order for an individual to receive treatment under the WTC Health Program, there must be an individual determination that the WTC attacks were "substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition."

Accordingly, the Special Master proposes that the Fund maintain and publish a list of presumptively covered conditions that resulted from the air crashes or debris removal, and that this list shall consist of the physical injuries and conditions that are found, under the WTC Health Program, to be WTC-related

health conditions. The Special Master will update this list so that it includes not only those physical conditions listed in Title I of the Zadroga Act, but also any additional physical conditions that the WTC Health Program determines to be WTC-related. The list of presumptively covered conditions will be published on the Fund's Web site.

The Special Master notes that as in the Fund's first iteration, the statute limits eligible injuries to those consisting of "physical harm." Accordingly, as in the Fund's first iteration, the statutory language does not permit the Fund to cover individuals with only mental and emotional injuries, even if the mental and emotional injuries are covered by the WTC Health Program.

Finally, the Special Master notes that the proposed regulations does not make the list of presumptively covered conditions the only conditions for which a claimant may seek coverage from the Fund. Where the claimant is otherwise eligible for an award and establishes extraordinary circumstances that were not adequately taken into account in the list of presumptively covered conditions, the proposed rules will permit the Special Master to find the claimant eligible even if the injury in question is not on the list of presumptively covered conditions. Because the list of presumptively covered conditions will be set based on the WTC Health Program's process for making decisions based on the best available science, it is anticipated that these instances will be rare.

II. Amendments of Claims

The 2001 Act provided that "not more than one claim may be submitted under this Title by an individual or on behalf of a deceased individual." The Zadroga Act did not amend this limitation. This provision does not appear to bar individuals who previously submitted claims from amending those earlier claims if additional relevant information has become available. The Special Master proposes that claimants be permitted to amend their claims to reflect the following circumstances:

(i) An injury that the claimant had not suffered (or did not reasonably know the claimant suffered) at the time the claimant filed the previous claim;

(ii) A condition that the Special Master has identified, since the time the claimant filed the previous claim, as a presumptively covered condition;

(iii) An injury for which the claimant was compensated by the Fund, but only if that injury has substantially worsened, resulting in damages or loss

that was not previously compensated; and;

(iv) Claims for which the individual is an eligible claimant as a result of amendments contained in the James Zadroga 9/11 Health and Compensation Act of 2010, Title II of Public Law 111–347.

Accordingly, the proposed regulations permit claimants to amend claims in those circumstances.

III. Awards and Prorating of Awards

The 2001 Act provides that the Fund will pay benefits for both "economic losses," which consist of pecuniary losses such as lost earnings, medical expenses, and other costs, and "noneconomic losses," which include losses for physical and emotional pain, suffering, and loss of companionship. The Zadroga Act did not amend those provisions; however, the Zadroga Act does limit the total amount of funds available for paying awards and prohibits the Fund from distributing more than a certain amount of compensation within the first five years.

(a) Advance Benefits

The 2001 rule included a provision for "advance benefits" for eligible claimants to be paid during the pendency of the claims process, in recognition of the exigency of the circumstances and the urgency of the need for providing some immediate compensation to those who, without a moment's notice, were physically injured and the families of those who were killed. The context at this point is different. The statute already contemplates two separate rounds of payments, one in the first five years and a second in the program's sixth year. Further, the administrative costs associated with additional rounds of payments reduce the funds available to pay claimants. Accordingly, the proposed rule does not include a provision for payment of advance benefits.

(b) Methodology for Calculating Awards

The determination of "economic losses" will be made, as in the Fund's first iteration, on a case-by-case basis according to the losses that each claimant has demonstrated. In the Fund's first iteration, the Special Master determined that the "noneconomic losses" of a claimant who was killed in the 9/11 crashes themselves would be \$250,000 plus an additional \$100,000 for each dependent. Those dollar values were consistent with the compensation that Congress made available under existing federal programs for certain citizens who have also died, often

without a moment's notice: public safety officers who are killed while on duty and members of our military who are killed in the line of duty while serving our nation. *See* 67 FR 11239 (Mar. 13, 2002). Those awards for noneconomic losses were presumed correct, but individuals were able to submit additional evidence that would justify a higher amount in a particular instance. For individuals who suffered physical injuries, rather than death, the noneconomic awards determined adjusted based on the extent and duration of the physical harm.

The Special Master proposes that the methodologies for establishing, and the compensation offered for, harms in the first iteration of the Fund are initially appropriate here. The Special Master will continue to consider whether noneconomic damages for such deaths should be adjusted.

(c) Proration of Awards

In the Zadroga Act, Congress appropriated \$2.775 billion to be provided by the Fund during this second iteration. Of this amount, the Act provides that only \$875 million may be spent during the program's first five years, with the remaining funds to be paid during the sixth year.

In order to ensure that the \$875 million cap is not exceeded during those first five years, the Zadroga Act requires the Special Master to ratably reduce the amount of compensation paid to claimants during that time to ensure that all claimants entitled to payment "receive a payment" during that period and to ensure that the \$875 million cap is not exceeded. The Act further requires that claimants whose payments are ratably reduced during this time are to receive a second payment in the year after the claims period has ended (July 1, 2016 to June 30, 2017), consisting of the difference between the amount that the claimant should have been paid under the Act and the reduced amount paid during the first five years. The regulations accordingly require the Special Master to prorate payments in a manner consistent with the statute, based on available information regarding potential future claims and available funds. The Special Master invites comments on the best manner to fulfill the statute's purposes in this respect.

IV. Procedure for Claims Evaluation

Because the \$2.775 billion appropriated by Congress for the Fund must pay for claimant awards as well as the Fund's administrative expenses, it is important for the Fund to keep administrative expenses low in order to

maximize the amount of funds available for claimants. Accordingly, the Special Master proposes eliminating one of the two procedures used previously for evaluating claims.

Previously, claimants could select one of two procedures: Track A or Track B. Under Track A, the Fund would determine eligibility and a presumed award based on the claimant's filings. The claimant could then either (1) accept the presumed award and request payment or (2) request a hearing for further review of the determination. Importantly, every claimant had the option of a hearing to determine whether the claimant's presumptive award was correct.

Under Track B, claimants proceeded directly to a hearing following a finding of eligibility. Only after that hearing would the Fund make an award determination, which was not subject to any further review or appeal.

The proposed regulations eliminate Track B. In doing so, the proposed regulations seek to reduce administrative expenses in order to maximize the funds available to pay claimants. Hearings are a substantial source of administrative expenses, and eliminating the initial hearing under Track B would still ensure that any claimant who wanted a hearing, after receiving his or her presumptive award, could receive one. Because some claimants who might have opted for a Track B initial hearing will find that they are satisfied with their presumptive award, some hearings will be avoided—and the costs associated with those hearings can instead be used to pay claimants.

V. Other Changes

The proposed regulations address a number of other issues. Among other things, the regulations address the ability of individuals who have settled civil actions to participate in the Fund, and the amounts that attorneys may charge claimants for services rendered in connection with a claim to the Fund. The Special Master invites comments on these and any other issues relating to the Fund.

Regulatory Certifications

Paperwork Reduction Act of 1995

This rule proposes to implement Title II of the Zadroga Act which reactivates the September 11th Victim Compensation Fund of 2001. In order to be able to evaluate claims and provide compensation, the Fund will need to collect information from an individual (or a personal representatives of a deceased individual) who suffered

physical harm or was killed as a result of the terrorist-related aircraft crashes of September 11, 2001 or the debris removal efforts that took place in the immediate aftermath of those crashes. Accordingly, the Department of Justice (DOJ), Civil Division will submit an information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995. The Department will also publish a Notice in the Federal Register soliciting public comment on the information collection associated with this rulemaking.

Regulatory Flexibility Act

These regulations set forth procedures by which the Federal government will award compensation benefits to eligible victims of the September 11, 2001 terrorist attacks. Under 5 U.S.C. 601(6), the term "small entity" does not include the Federal government, the party charged with incurring the costs attendant to the implementation and administration of the Victims Compensation Fund. Accordingly, the Department has reviewed this rule in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities because it provides compensation to eligible individuals who were physically injured as a result of the terrorist-related aircraft crashes of September 11, 2001, and compensation through a "personal representative" for those who were killed as a result of those crashes. This rule provides compensation to individuals, not to entities.

Executive Orders 12866 and 13563—Regulatory Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review" section 1(b), Principles of Regulation and in accordance with Executive Order 13563 "Improving Regulation and Regulatory Review" section 1(b) General Principles of Regulation.

The Department of Justice has determined that this rule is an "economically significant regulatory action" under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has been reviewed by the Office of Management and Budget.

Further, both Executive Orders 12866 and 13563 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, distributive 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. The Department has assessed the costs and benefits of this regulation and believes that the regulatory approach selected maximizes net benefits.

Assessment of Benefits, Costs, and Alternatives.

As required by Executive Order 13563 and Executive Order 12866 for economically significant regulatory actions, the Department has assessed the benefits and costs anticipated from this rulemaking and considered whether there are reasonably feasible alternatives to this rulemaking, including considering whether there are reasonably viable non-regulatory actions that could be taken in lieu of this rulemaking. The purpose of this rulemaking is to provide the legal and administrative framework necessary to provide compensation to any individual (or a personal representative of a deceased individual) who suffered physical harm or was killed as a result of the terrorist-related aircraft crashes of September 11, 2001 or the debris removal efforts that took place in the immediate aftermath of those crashes, as provided by Title II of the Zadroga Act. The primary benefits and costs of this rulemaking are both set by statute as Congress has appropriated a capped amount—\$2.775 billion payable over a period of years—for this program. Because the \$2.775 billion appropriated by Congress for the Fund must pay for claimant awards as well as the Fund's administrative expenses, it is important for the Fund to keep administrative expenses low in order to maximize the amount of funds available for claimants. Finally, based on past practice with the operation of the original Fund and the necessity to establish the legal and administrative framework for the reopened Fund, the Department concludes that there are no viable non-regulatory actions that it could take to implement the Zadroga Act in a fair and efficient manner.

Executive Order 13132—Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and

responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. However, the Department of Justice has worked cooperatively with state and local officials in the affected communities in the preparation of this rule. Also, the Department individually notified national associations representing elected officials regarding this rulemaking.

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 104

Disaster assistance, Disability benefits, Terrorism.

Accordingly, for the reasons set forth in the preamble, Part 104 of chapter I of Title 28 of the Code of Federal Regulations is proposed to be amended by revising part 104 to read as follows:

PART 104—SEPTEMBER 11TH VICTIM COMPENSATION FUND

Subpart A—General; Eligibility

- 104.1 Purpose.
- 104.2 Eligibility definitions and requirements.
- 104.3 Other definitions.
- 104.4 Personal Representative.
- 104.5 Foreign claims.

104.6 Amendments to this part.

Subpart B—Filing for Compensation

- 104.21 Presumptively covered conditions.
- 104.22 Filing for compensation.

Subpart C—Claim Intake, Assistance, and Review Procedures

- 104.31 Procedure for claims evaluation.
- 104.32 Eligibility review.
- 104.33 Hearing.
- 104.34 Publication of awards.
- 104.35 Claims deemed abandoned by claimants.

Subpart D—Amount of Compensation for Eligible Claimants

- 104.41 Amount of compensation.
- 104.42 Applicable state law.
- 104.43 Determination of presumed economic loss for decedents.
- 104.44 Determination of presumed noneconomic losses for decedents.
- 104.45 Determination of presumed economic loss for claimants who suffered physical harm.
- 104.46 Determination of presumed noneconomic losses for claimants who suffered physical harm.
- 104.47 Collateral sources.

Subpart E—Payment of Claims

- 104.51 Payments to eligible individuals.
- 104.52 Distribution of award to decedent's beneficiaries.

Subpart F—Limitations

- 104.61 Limitation on civil actions.
- 104.62 Time limit on filing claims.
- 104.63 Subrogation.

Subpart G—Measures To Protect the Integrity of the Compensation Program

- 104.71 Procedures to prevent and detect fraud.

Subpart H—Attorney Fees

- 104.81 Limitation on attorney fees.

Authority: Title IV of Pub. L. 107–42, 115 Stat. 230, 49 U.S.C. 40101 note; Title II of Pub.L. 111–347, 124 Stat. 3623.

Subpart A—General; Eligibility

§ 104.1 Purpose.

This part implements the provisions of the September 11th Victim Compensation Fund of 2001, Title IV of Public Law 107–42, 115 Stat. 230 (Air Transportation Safety and System Stabilization Act), as amended by the James Zadroga 9/11 Health and Compensation Act of 2010, Title II of Public Law 111–347, to provide compensation to eligible individuals who were physically injured as a result of the terrorist-related aircraft crashes of September 11, 2001 or debris removal during the immediate aftermath of those crashes, and to the “personal representatives” of those who were killed as a result of the crashes. All compensation provided through the Fund will be on account of personal physical injuries or death.

§ 104.2 Eligibility definitions and requirements.

(a) *Eligible claimants.* The term eligible claimants means:

- (1) Individuals present at a 9/11 crash site at the time of or in the immediate aftermath of the terrorist-related aircraft crashes and who suffered physical harm, as defined herein, as a direct result of the crashes or debris removal;
- (2) The Personal Representatives of deceased individuals aboard American Airlines flights 11 or 77 and United Airlines flights 93 or 175; and
- (3) The Personal Representatives of individuals who were present at a 9/11 crash site at the time of or in the immediate aftermath of the crashes and who died as a direct result of the terrorist-related aircraft crash.

(4) The term eligible claimants does not include any individual or representative of an individual who is identified to have been a participant or conspirator in the terrorist-related crashes of September 11.

(b) *Immediate aftermath.* The term immediate aftermath means any period beginning with the terrorist-related aircraft crashes of September 11, 2001, and ending on May 30, 2002.

(c) *Physical harm.* (1) The term physical harm shall mean a physical injury to the body that was treated by a medical professional within a reasonable time from the date of discovering such harm; and

(2) The physical injury must be verified by medical records created by or at the direction of the medical professional who provided the medical care contemporaneously with the care.

(d) *Personal Representative.* The term Personal Representative shall mean the person determined to be the Personal Representative under § 104.4 of this part.

(e) *WTC Health Program.* The term WTC Health Program means the World Trade Center Health Program established by Title I of Public Law 111–347 (codified at Title XXXIII of the Public Health Service Act, 42 U.S.C. 300mm–300mm–61).

(f) *WTC-related health condition.* The term WTC-related health condition means those health conditions identified as WTC-related by Title I of Public Law 111–347 and by regulations implementing that Title.

(g) *9/11 crash site.* The term 9/11 crash site means:

- (1) The World Trade Center site, Pentagon site, and Shanksville, Pennsylvania site; or
- (2) The buildings or portions of buildings that were destroyed as a result of the terrorist-related airplane crashes of September 11, 2001; or

(3) The area in Manhattan south of the line that runs along Reade Street from the Hudson River to the intersection of Reade Street and Centre Street, south on Centre Street to the Brooklyn Bridge, and along the Brooklyn Bridge, or any other area contiguous to the crash sites that the Special Master determines was sufficiently close to the site that there was a demonstrable risk of physical harm resulting from the impact of the aircraft or any subsequent fire, explosions, or building collapses (including the immediate area in which the impact occurred, fire occurred, portions of buildings fell, or debris fell upon and injured individuals); or

(4) Any area related to, or along, routes of debris removal, such as barges and Fresh Kills.

§ 104.3 Other definitions.

(a) *Beneficiary*. The term beneficiary shall mean a person to whom the Personal Representative shall distribute all or part of the award under § 104.52 of this Part.

(b) *Dependents*. The Special Master shall identify as dependents those persons so identified by the victim on his or her federal tax return for the year prior to the year of the victim's death (or those persons who legally could have been identified by the victim on his or her federal tax return for the year prior to the year of the victim's death) unless:

(1) The claimant demonstrates that a minor child of the victim was born or adopted on or after January 1 of the year of the victim's death;

(2) Another person became a dependent in accordance with then-applicable law on or after January 1 of the year of the victim's death; or

(3) The victim was not required by law to file a federal income tax return for the year prior to the year of the victim's death.

(c) *Spouse*. The Special Master shall identify as the spouse of a victim the person reported as spouse on the victim's federal tax return for the year prior to the year of the victim's death (or the person who legally could have been identified by the victim on his or her federal tax return for the year prior to the year of the victim's death) unless:

(1) The victim was married or divorced in accordance with applicable state law on or after January 1 of the year of the victim's death; or

(2) The victim was not required by law to file a federal income tax return for the year prior to the year of the victim's death.

(d) *The Act*. The Act, as used in this part, shall mean Public Law 107-42, 115 Stat. 230 ("Air Transportation Safety and System Stabilization Act"), 49

U.S.C. 40101 note, as amended by the James Zadroga 9/11 Health and Compensation Act of 2010, Title II of Public Law 111-347.

(e) *Victim*. The term victim shall mean an eligible injured claimant or a decedent on whose behalf a claim is brought by an eligible Personal Representative.

(f) *Substantially Complete*. A claim becomes substantially complete when, in the opinion of the Special Master or her designee, the claim contains sufficient information and documentation to determine both the claimant's eligibility and, if the claimant is eligible, an appropriate award.

§ 104.4 Personal Representative.

(a) *In general*. The Personal Representative shall be:

(1) An individual appointed by a court of competent jurisdiction as the Personal Representative of the decedent or as the executor or administrator of the decedent's will or estate.

(2) In the event that no Personal Representative or executor or administrator has been appointed by any court of competent jurisdiction, and such issue is not the subject of pending litigation or other dispute, the Special Master may, in her discretion, determine that the Personal Representative for purposes of compensation by the Fund is the person named by the decedent in the decedent's will as the executor or administrator of the decedent's estate. In the event no will exists, the Special Master may, in her discretion, determine that the Personal Representative for purposes of compensation by the Fund is the first person in the line of succession established by the laws of the decedent's domicile governing intestacy.

(b) *Notice to beneficiaries*. (1) Any purported Personal Representative must, before filing an Eligibility Form, provide written notice of the claim (including a designated portion of the Eligibility Form) to the immediate family of the decedent (including, but not limited to, the decedent's spouse, former spouses, children, other dependents, and parents), to the executor, administrator, and beneficiaries of the decedent's will, and to any other persons who may reasonably be expected to assert an interest in an award or to have a cause of action to recover damages relating to the wrongful death of the decedent.

(2) Personal delivery or transmission by certified mail, return receipt requested, shall be deemed sufficient notice under this provision. The claim

forms shall require that the purported Personal Representative certify that such notice (or other notice that the Special Master deems appropriate) has been given. In addition, as provided in § 104.21(b)(5) of this part, the Special Master may publish a list of individuals who have filed Eligibility Forms and the names of the victims for whom compensation is sought, but shall not publish the content of any such form.

(c) *Objections to Personal Representatives*. Objections to the authority of an individual to file as the Personal Representative of a decedent may be filed with the Special Master by parties who assert a financial interest in the award up to 30 days following the filing by the Personal Representative. If timely filed, such objections shall be treated as evidence of a "dispute" pursuant to paragraph (d) of this section.

(d) *Disputes as to identity*. The Special Master shall not be required to arbitrate, litigate, or otherwise resolve any dispute as to the identity of the Personal Representative. In the event of a dispute over the appropriate Personal Representative, the Special Master may suspend adjudication of the claim or, if sufficient information is provided, calculate the appropriate award and authorize payment, but place in escrow any payment until the dispute is resolved either by agreement of the disputing parties or by a court of competent jurisdiction. Alternatively, the disputing parties may agree in writing to the identity of a Personal Representative to act on their behalf, who may seek and accept payment from the Fund while the disputing parties work to settle their dispute.

§ 104.5 Foreign claims.

In the case of claims brought by or on behalf of foreign citizens, the Special Master may alter the requirements for documentation set forth herein to the extent such materials are unavailable to such foreign claimants.

§ 104.6 Amendments to this part.

Claimants are entitled to have their claims processed in accordance with the provisions of this Part that were in effect at the time that their claims were submitted under § 104.22(d). All claims will be processed in accordance with the current provisions of this Part, unless the claimant has notified the Special Master that he or she has elected to have the claim resolved under the regulations that were in effect at the time that the claim was submitted under § 104.22(d).

Subpart B—Filing for Compensation**§ 104.21 Presumptively covered conditions.**

(a) *In general.* The Special Master shall maintain and publish on the Fund's Web site a list of presumptively covered conditions that resulted from the terrorist-related air crashes of September 11, 2001, or debris removal. The list shall consist of physical injuries that are determined to be WTC-related health conditions by the WTC Health Program.

(b) *Updates.* The Special Master shall update the list of presumptively covered conditions as the list of WTC-related health conditions by the WTC Health Program is updated. Claims may then be amended pursuant to § 104.22(e)(ii).

(c) *Conditions other than presumptively covered conditions.* A claimant may also be eligible for payment under § 104.51 where the claimant—

(1) Presents extraordinary circumstances not adequately addressed by the list of presumptively covered conditions; and

(2) Is otherwise eligible for payment.

§ 104.22 Filing for compensation.

(a) *Compensation form; "filing."* A claim shall be deemed "filed" for purposes of section 405(b)(3) of the Act (providing that the Special Master shall issue a determination regarding the matters that were the subject of the claim not later than 120 calendar days after the date on which a claim is filed), and for any time periods in this part, when it is substantially complete.

(b) *Eligibility Form.* The Special Master shall develop an Eligibility Form that will require the claimant to provide information necessary for determining the claimant's eligibility to recover from the Fund.

(1) The Eligibility Form may require that the claimant certify that he or she has dismissed any pending lawsuit seeking damages as a result of the terrorist-related airplane crashes of September 11, 2001, or for damages arising from or related to debris removal (except for actions seeking collateral source benefits) within 90 days of the effective date of this part pursuant to section 405(c)(3)(C)(ii) of the Act and that there is no pending lawsuit brought by a dependent, spouse, or beneficiary of the victim.

(2) The Special Master may require as part of the notice requirement pursuant to § 104.4(b) that the claimant provide copies of a designated portion of the Eligibility Form to the immediate family of the decedent (including, but not limited to, the spouse, former spouses,

children, other dependents, and parents), to the executor, administrator, and beneficiaries of the decedent's will, and to any other persons who may reasonably be expected to assert an interest in an award or to have a cause of action to recover damages relating to the wrongful death of the decedent.

(3) The Eligibility Form may require claimants to provide the following proof:

(i) Proof of death: Death certificate or similar official documentation;

(ii) Proof of presence at site: Documentation sufficient to establish presence at a 9/11 crash site, which may include, without limitation, a death certificate, proof of residence, records of employment or school attendance, contemporaneous medical records, contemporaneous records of federal, state, city or local government, an affidavit or declaration of the decedent's or injured claimant's employer, or other sworn statement (or unsworn statement complying with 28 U.S.C. 1746) regarding the presence of the victim;

(iii) Proof of physical harm: Certification of a conclusion by the WTC Health Program that the claimant suffers from a WTC-related health condition; a health form provided by the Fund and completed by a licensed medical professional.

(iv) Personal Representative: Copies of relevant legal documentation, including court orders; letters testamentary or similar documentation; proof of the purported Personal Representative's relationship to the decedent; copies of wills, trusts, or other testamentary documents; and information regarding other possible beneficiaries as requested by the Eligibility Form;

(v) Any other information that the Special Master deems necessary to determine the claimant's eligibility.

(4) The Special Master may also require waivers, consents, or authorizations from claimants to obtain directly from third parties tax returns, medical information, employment information, or other information that the Special Master deems relevant in determining the claimant's eligibility or award, and may request an opportunity to review originals of documents submitted in connection with the Fund.

(5) The Special Master may publish a list of individuals who have filed Eligibility Forms and the names of the victims for whom compensation is sought, but shall not publish the content of any such form.

(c) *Personal Injury Compensation Form and Death Compensation Form.* The Special Master shall develop a Personal Injury Compensation Form that each injured claimant must submit. The

Special Master shall also develop a Death Compensation Form that each Personal Representative must submit. These forms shall require the claimant to provide certain information that the Special Master deems necessary to determining the amount of any award, including information concerning income, collateral sources, benefits, settlements and attorneys' fees relating to civil actions described in section 405(c)(3)(C)(iii) of the Act, and other financial information, and shall require the claimant to state the factual basis for the amount of compensation sought. It shall also allow the claimant to submit certain other information that may be relevant, but not necessary, to the determination of the amount of any award.

(1) Claimants shall, at a minimum, submit all tax returns that were filed for the period beginning three years prior to the year of death or discovery of the injury and ending with the year the claim was filed or the year of death. The Special Master may, at the Special Master's discretion, require that claimants submit copies of tax returns or other records for any other period of years the Special Master deems appropriate for determination of an award. The Special Master may also require waivers, consents, or authorizations from claimants to obtain directly from third parties medical information, employment information, or other information that the Special Master deems relevant to determining the amount of any award.

(2) Claimants may attach to the "Personal Injury Compensation Form" or "Death Compensation Form" any additional statements, documents or analyses by physicians, experts, advisors, or any other person or entity that the claimant believes may be relevant to a determination of compensation.

(d) *Submission of a claim.* Section 405(c)(3)(C) of the Act provides that upon the submission of a claim under the Fund, the claimant waives the right to file a civil action (or to be a party to an action) in any Federal or State court for damages sustained as a result of the terrorist-related aircraft crashes of September 11, 2001, except for civil actions to recover collateral source obligations and civil actions against any person who is a knowing participant in any conspiracy to hijack any aircraft or commit any terrorist act. A claim shall be deemed submitted for purposes of section 405(c)(3)(C) of the Act when the claim is deemed filed pursuant to § 104.21, regardless of whether any time limits are stayed or tolled.

(e) *Amendment of claims.* A claimant who has previously submitted a claim may amend such claim to include

(1) An injury that the claimant had not suffered (or did not reasonably know the claimant suffered) at the time the claimant filed the previous claim;

(2) A condition that the Special Master has identified and published in accordance with 104.21(a), since the time the claimant filed the previous claim, as a presumptively covered condition;

(3) An injury for which the claimant was previously compensated by the Fund, but only if that injury has substantially worsened, resulting in damages or loss that was not previously compensated; and

(4) Claims for which the individual is an eligible claimant as a result of amendments contained in the James Zadroga 9/11 Health and Compensation Act of 2010, Title II of Public Law 111–347.

(f) *Provisions of information by third parties.* Any third party having an interest in a claim brought by a Personal Representative may provide written statements or information regarding the Personal Representative's claim. The Claims Evaluator or the Special Master or the Special Master's designee may, at his or her discretion, include the written statements or information as part of the claim.

Subpart C—Claim Intake, Assistance, and Review Procedures

§ 104.31 Procedure for claims evaluation.

(a) *Initial review.* Claims Evaluators shall review the forms filed by the claimant and either deem the claim “filed” (pursuant to § 104.21(a)) or notify the claimant of any deficiency in the forms or any required documents.

(b) *Procedure.* The Claims Evaluator shall determine eligibility and the claimant's presumed award pursuant to §§ 104.43 to 104.46 of this part and, within 75 days of the date the claim was deemed filed, notify the claimant in writing of the eligibility determination, the amount of the presumed award, and the right to request a hearing before the Special Master or her designee under § 104.33 of this part. After an eligible claimant has been notified of the presumed award, within 30 days the claimant may either accept the presumed compensation determination as the final determination and request payment, or may instead request a review before the Special Master or her designee pursuant to § 104.33. Claimants found to be ineligible may appeal pursuant to § 104.32.

(c) *Multiple claims from the same family.* The Special Master may treat claims brought by or on behalf of two or more members of the same immediate family as related or consolidated claims for purposes of determining the amount of any award.

§ 104.32 Eligibility review.

Any claimant deemed ineligible by the Claims Evaluator may appeal that decision to the Special Master or her designee by filing an eligibility appeal within 30 days on forms created by the office of the Special Master.

§ 104.33 Hearing.

(a) *Supplemental submissions.* The claimant may prepare and file Supplemental Submissions within 21 calendar days from notification of the presumed award. The Special Master shall develop forms appropriate for Supplemental Submissions.

(b) *Conduct of hearings.* Hearings shall be before the Special Master or her designee. The objective of hearings shall be to permit the claimant to present information or evidence that the claimant believes is necessary to a full understanding of the claim. The claimant may request that the Special Master or her designee review any evidence relevant to the determination of the award, including without limitation: The nature and extent of the claimant's injury; evidence of the claimant's presence at a 9/11 crash site; factors and variables used in calculating economic loss; the identity of the victim's spouse and dependents; the financial needs of the claimant; facts affecting noneconomic loss; and any factual or legal arguments that the claimant contends should affect the award. Claimants shall be entitled to submit any statements or reports in writing. The Special Master or her designee may require authentication of documents, including medical records and reports, and may request and consider information regarding the financial resources and expenses of the victim's family or other material that the Special Master or her designee deems relevant.

(c) *Location and duration of hearings.* The hearings shall, to the extent practicable, be scheduled at times and in locations convenient to the claimant or his or her representative. The hearings shall be limited in length to a time period determined by the Special Master or her designee.

(d) *Witnesses, counsel, and experts.* Claimants shall be permitted, but not required, to present witnesses, including expert witnesses. The Special Master or her designee shall be

permitted to question witnesses and examine the credentials of experts. The claimant shall be entitled to be represented by an attorney in good standing, but it is not necessary that the claimant be represented by an attorney. All testimony shall be taken under oath.

(e) *Waivers.* The Special Master shall have authority and discretion to require any waivers necessary to obtain more individualized information on specific claimants.

(f) *Award Appeals.* For award appeals, the Special Master or her designee shall make a determination whether:

(1) There was an error in determining the presumptive award, either because the claimant's individual criteria were misapplied or for another reason; or

(2) The claimant presents extraordinary circumstances not adequately addressed by the presumptive award.

(g) *Determination.* The Special Master shall notify the claimant in writing of the final amount of the award, but need not create or provide any written record of the deliberations that resulted in that determination. There shall be no further review or appeal of the Special Master's determination. In notifying the claimant of the final amount of the award, the Special Master may designate the portions or percentages of the final award that are attributable to economic loss and non-economic loss, respectively, and may provide such other information as appropriate to provide adequate guidance for a court of competent jurisdiction and a personal representative.

§ 104.34 Publication of awards.

The Special Master reserves the right to publicize the amounts of some or all of the awards, but shall not publish the name of the claimants or victims that received each award. If published, these decisions would be intended by the Special Master as general guides for potential claimants and should not be viewed as precedent binding on the Special Master or her staff.

§ 104.35 Claims deemed abandoned by claimants.

The Special Master and her staff will endeavor to evaluate promptly any information submitted by claimants. Nonetheless, it is the responsibility of the claimant to keep the Special Master informed of his or her current address and to respond within the duration of this five-year program to requests for additional information. Claims outstanding at the end of this program because of a claimant's failure to

complete his or her filings shall be deemed abandoned.

Subpart D—Amount of Compensation for Eligible Claimants

§ 104.41 Amount of compensation.

As provided in section 405(b)(1)(B)(ii) of the Act, in determining the amount of compensation to which a claimant is entitled, the Special Master shall take into consideration the harm to the claimant, the facts of the claim, and the individual circumstances of the claimant. The individual circumstances of the claimant may include the financial needs or financial resources of the claimant or the victim's dependents and beneficiaries. As provided in section 405(b)(6) of the Act, the Special Master shall reduce the amount of compensation by the amount of collateral source compensation the claimant (or, in the case of a Personal Representative, the victim's beneficiaries) has received or is entitled to receive as a result of the terrorist-related aircraft crashes of September 11, 2001. In no event shall an award (before collateral source compensation has been deducted) be less than \$500,000 in any case brought on behalf of a deceased victim with a spouse or dependent, or \$300,000 in any case brought on behalf of a deceased victim who was single with no dependents.

§ 104.42 Applicable state law.

The phrase "to the extent recovery for such loss is allowed under applicable state law," as used in the statute's definition of economic loss in section 402(5) of the Act, is interpreted to mean that the Special Master is not permitted to compensate claimants for those categories or types of economic losses that would not be compensable under the law of the state that would be applicable to any tort claims brought by or on behalf of the victim.

§ 104.43 Determination of presumed economic loss for decedents.

In reaching presumed determinations for economic loss for Personal Representatives bringing claims on behalf of decedents, the Special Master shall consider sums corresponding to the following:

(a) *Loss of earnings or other benefits related to employment.* The Special Master, as part of the process of reaching a "determination" pursuant to section 405(b) of the Act, shall develop a methodology and publish schedules, tables, or charts that will permit prospective claimants to estimate determinations of loss of earnings or other benefits related to employment based upon individual circumstances of

the deceased victim, including: The age of the decedent as of the date of death; the number of dependents who survive the decedent; whether the decedent is survived by a spouse; and the amount and nature of the decedent's income for recent years. The Decedent's salary/income in the three years preceding the year of death (or for other years the Special Master deems relevant) shall be evaluated in a manner that the Special Master deems appropriate. The Special Master may, if she deems appropriate, take an average of income figures for the three years preceding the year of death, and may also consider income for other periods that she deems appropriate, including published pay scales for victims who were government or military employees. The Special Master's methodology and schedules, tables, or charts shall yield presumed determinations of loss of earnings or other benefits related to employment for annual incomes up to but not beyond the 98th percentile of individual income in the United States for the year preceding the year of death. In cases where the victim was a minor child, the Special Master may assume an average income for the child commensurate with the average income of all wage earners in the United States. For victims who were members of the armed services or government employees such as firefighters or police officers, the Special Master may consider all forms of compensation (or pay) to which the victim was entitled. For example, military service members' and uniformed service members' compensation includes all of the various components of compensation, including, but not limited to, basic pay (BPY), basic allowance for housing (BAH), basic allowance for subsistence (BAS), federal income tax advantage (TAD), overtime bonuses, differential pay, and longevity pay.

(b) *Medical expense loss.* This loss equals the out-of-pocket medical expenses that were incurred as a result of the physical harm suffered by the victim (i.e., those medical expenses that were not paid for or reimbursed through health insurance or other programs for which the claimant was not charged). This loss shall be calculated on a case-by-case basis, using documentation and other information submitted by the Personal Representative.

(c) *Replacement services loss.* For decedents who did not have any prior earned income, or who worked only part time outside the home, economic loss may be determined with reference to replacement services and similar measures.

(d) *Loss due to death/burial costs.* This loss shall be calculated on a case-by-case basis, using documentation and other information submitted by the personal representative and includes the out-of-pocket burial costs that were incurred.

(e) *Loss of business or employment opportunities.* Such losses shall be addressed through the procedure outlined above in paragraph (a) of this section.

§ 104.44 Determination of presumed noneconomic losses for decedents.

The presumed non-economic losses for decedents shall be \$250,000 plus an additional \$100,000 for the spouse and each dependent of the deceased victim. Such presumed losses include a noneconomic component of replacement services loss.

§ 104.45 Determination of presumed economic loss for claimants who suffered physical harm.

In reaching presumed determinations for economic loss for claimants who suffered physical harm (but did not die), the Special Master shall consider sums corresponding to the following:

(a) *Loss of earnings or other benefits related to employment.* The Special Master may determine the loss of earnings or other benefits related to employment on a case-by-case basis, using documentation and other information submitted by the claimant, regarding the actual amount of work that the claimant has missed or will miss without compensation. Alternatively, the Special Master may determine the loss of earnings or other benefits related to employment by relying upon the methodology created pursuant to § 104.43(a) and adjusting the loss based upon the extent of the victim's physical harm.

(1) *Disability; in general.* In evaluating claims of disability, the Special Master will, in general, make a determination regarding whether the claimant is capable of performing his or her usual profession in light of the injuries.

(2) *Total permanent disability.* With respect to claims of total permanent disability, the Special Master may accept a determination of disability made by the Social Security Administration as evidence of disability without any further medical evidence or review. The Special Master may also consider determinations of permanent total disability made by other governmental agencies or private insurers in evaluating the claim. The Special Master may require that the claimant submit an evaluation of the claimant's disability and ability to

perform his or her occupation prepared by medical experts.

(3) Partial disability. With respect to claims of partial disability, the Special Master may consider evidence of the effect of the partial disability on the claimant's ability to perform his or her usual occupation as well as the effect of the partial disability on the claimant's ability to participate in usual daily activities.

(b) *Medical Expense Loss*. This loss equals the out-of-pocket medical expenses that were incurred as a result of the physical harm suffered by the victim (i.e., those medical expenses that were not paid for or reimbursed through health insurance or other programs for which the claimant was not charged). In addition, this loss equals future out-of-pocket medical expenses that will be incurred as a result of the physical harm suffered by the victim (i.e., those medical expenses that will not be paid for or reimbursed through health insurance). These losses shall be calculated on a case-by-case basis, using documentation and other information submitted by the claimant.

(c) *Replacement services loss*. For injured claimants who did not have any prior earned income, or who worked only part-time outside the home, economic loss may be determined with reference to replacement services and similar measures.

(d) *Loss of business or employment opportunities*. Such losses shall be addressed through the procedure outlined above in paragraph (a) of this section.

§ 104.46 Determination of presumed noneconomic losses for claimants who suffered physical harm.

The Special Master may determine the presumed noneconomic losses for claimants who suffered physical harm (but did not die) by relying upon the noneconomic losses described in § 104.44 and adjusting the losses based upon the extent of the victim's physical harm. Such presumed losses include any noneconomic component of replacement services loss.

§ 104.47 Collateral sources.

(a) *Payments that constitute collateral source compensation*. The amount of compensation shall be reduced by all collateral source compensation, including life insurance, pension funds, death benefits programs, payments by Federal, State, or local governments related to the terrorist-related aircraft crashes of September 11, 2001 or debris removal, including under the World Trade Center Health Program established under section 3001 of the

Public Health Service Act, and payments made pursuant to the settlement of a civil action as described in section 405(c)(3)(C)(iii) of the Act. In determining the appropriate collateral source offset for future benefit payments, the Special Master may employ an appropriate methodology for determining the present value of such future benefits. In determining the appropriate value of offsets for pension funds, life insurance and similar collateral sources, the Special Master may, as appropriate, reduce the amount of offsets to take account of self-contributions made or premiums paid by the victim during his or her lifetime. In determining the appropriate collateral source offset for future benefit payments that are contingent upon one or more future event(s), the Special Master may reduce such offsets to account for the possibility that the future contingencies may or may not occur. In cases where the recipients of collateral source compensation are not beneficiaries of the awards from the Fund, the Special Master shall have discretion to exclude such compensation from the collateral source offset where necessary to prevent beneficiaries from having their awards reduced by collateral source compensation that they will not receive.

(b) *Payments that do not constitute collateral source compensation*. The following payments received by claimants do not constitute collateral source compensation:

(1) The value of services or in-kind charitable gifts such as provision of emergency housing, food, or clothing; and

(2) Charitable donations distributed to the beneficiaries of the decedent, to the injured claimant, or to the beneficiaries of the injured claimant by privately funded charitable entities; provided however, that the Special Master may determine that funds provided to victims or their families through a privately funded charitable entity constitute, in substance, a payment described in paragraph (a) of this section.

(3) Tax benefits received from the Federal government as a result of the enactment of the Victims of Terrorism Tax Relief Act.

Subpart E—Payment of Claims

§ 104.51 Payments to eligible individuals.

(a) *Payment date*. Subject to subsection (c) of this section, the Special Master shall authorize payment of an award to a claimant not later than 20 days after the date on which:

(1) The claimant accepts the presumed award; or

(2) A final award for the claimant is determined after a hearing on appeal.

(b) *Failure to accept or appeal presumed award*. If a claimant fails to accept or appeal the presumed award determined for that claimant within 30 days, the presumed award shall be deemed to have been accepted and all rights to appeal the award shall have been waived.

(c) *Pro-rata and payment of remaining claims*. The James Zadroga 9/11 Health and Compensation Act of 2010, Title II of Public Law 111-347, requires that the total amount of Federal funds paid for expenditures including compensation with respect to claims filed on or after [OPEN DATE], 2011 will not exceed \$2,775,000,000. Furthermore, the total amount of Federal funds expended during the period from [EFFECTIVE DATE OF FINAL RULE], through [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE], may not exceed \$875,000,000.

(1) *In general*. The Special Master shall ratably reduce the amount of compensation due claimants in a manner to ensure, to the extent possible, that all claimants who are determined to be entitled to a payment receive a payment during the period from [EFFECTIVE DATE OF FINAL RULE], to [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE], and that the total amount of all such payments made during that 5-year period do not exceed the amount available under law during that period. The Special Master may periodically adjust the method of ratable reduction in light of available information regarding potential future claims and available funds.

(2) *Subsequent payments*. Subject to paragraph (c)(3) of this section, in any case in which the amount of a claim is ratably reduced pursuant to paragraph (c)(1) of this section, on or after [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE], but in no event later than [DATE 6 YEARS AFTER EFFECTIVE DATE OF FINAL RULE], the Special Master shall pay to the claimant the amount that is equal to the difference between:

(i) The amount that the claimant would have been paid under the presumed award; and

(ii) The amount the claimant was paid during the period from [EFFECTIVE DATE OF FINAL RULE], 2011 to [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

(3) In the event that the total amount of all claims under paragraph (c)(2) of this section exceeds the amount available under law, the Special Master

shall ratably reduce the amount of compensation due claimants in a manner to ensure, to the extent possible, that all claimants who are determined to be entitled to an additional payment receive their pro-rated share of the available funds.

§ 104.52 Distribution of award to decedent's beneficiaries.

The Personal Representative shall distribute the award in a manner consistent with the law of the decedent's domicile or any applicable rulings made by a court of competent jurisdiction. The Personal Representative shall, before payment is authorized, provide to the Special Master a plan for distribution of any award received from the Fund. Notwithstanding any other provision of these regulations or any other provision of state law, in the event that the Special Master concludes that the Personal Representative's plan for distribution does not appropriately compensate the victim's spouse, children, or other relatives, the Special Master may direct the Personal Representative to distribute all or part of the award to such spouse, children, or other relatives.

Subpart F—Limitations

§ 104.61 Limitation on civil actions.

(a) *General.* Section 405(c)(3)(C) of the Act provides that upon the submission of a claim under the Fund, the claimant waives the right to file a civil action (or be a party to an action) in any Federal or State court for damages sustained as a result of the terrorist-related aircraft crashes of September 11, 2001, or for damages arising from or related to debris removal, except that this limitation does not apply to recover collateral source obligations, or to a civil action against any person who is a knowing participant in any conspiracy to hijack any aircraft or commit any terrorist act. The Special Master shall take appropriate steps to inform potential claimants of section 405(c)(3)(C) of the Act.

(b) *Pending actions.* Claimants who have filed a civil action or who are a party to such an action as described in paragraph (a) of this section may not file a claim with the Special Master unless they withdraw from such action not later than [DATE 90 DAYS AFTER EFFECTIVE DATE OF FINAL RULE].

(c) *Settled actions.* In the case of an individual who settled a civil action described in Section 405(c)(3)(C) of the Act, such individual may not submit a claim under this title unless such action was commenced after December 22, 2003, and a release of all claims in such

action was tendered prior to January 2, 2011.

§ 104.62 Time limit on filing claims.

(a) *In general.* A claim may be filed by an individual (or by a personal representative on behalf of a deceased individual) during the period beginning on [EFFECTIVE DATE OF FINAL RULE], and ending on [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE], as follows:

(1) In the case that the individual knew (or reasonably should have known) before [EFFECTIVE DATE OF FINAL RULE], 2011 that the individual suffered a physical harm at a 9/11 crash site as a result of the terrorist-related aircraft crashes of September 11, 2001, or as a result of debris removal, and that the individual knew (or should have known) before such specified date that the individual was eligible to file a claim under this title, the individual may file a claim not later than [DATE 2 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

(2) In the case that the individual first knew (or reasonably should have known) on or after [EFFECTIVE DATE OF FINAL RULE], that the individual suffered such a physical harm or that the individual first knew (or should have known) on or after that date that the individual was eligible to file a claim under this title, the individual may file a claim not later than the last day of the 2-year period beginning on the date that the individual first knew (or should have known) that the individual both suffered from such harm and was eligible to file a claim under this title, but in no event beyond [DATE 5 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

(b) *Determination by Special Master.* The Special Master or the Special Master's designee should determine the timeliness of all claims under paragraph (a) of this section.

§ 104.63 Subrogation.

Compensation under this Fund does not constitute the recovery of tort damages against a third party nor the settlement of a third party action, and the United States shall be subrogated to all potential claims against third party tortfeasors of any victim receiving compensation from the Fund. For that reason, no person or entity having paid other benefits or compensation to or on behalf of a victim shall have any right of recovery, whether through subrogation or otherwise, against the compensation paid by the Fund.

Subpart G—Measures To Protect the Integrity of the Compensation Program

§ 104.71 Procedures to prevent and detect fraud.

(a) *Review of claims.* For the purpose of detecting and preventing the payment of fraudulent claims and for the purpose of assuring accurate and appropriate payments to eligible claimants, the Special Master shall implement procedures to:

(1) Verify, authenticate, and audit claims;

(2) Analyze claim submissions to detect inconsistencies, irregularities, duplication, and multiple claimants; and

(3) Ensure the quality control of claims review procedures.

(b) *Quality control.* The Special Master shall institute periodic quality control audits designed to evaluate the accuracy of submissions and the accuracy of payments, subject to the oversight of the Inspector General of the Department of Justice.

(c) *False or fraudulent claims.* The Special Master shall refer all evidence of false or fraudulent claims to appropriate law enforcement authorities.

Subpart H—Attorney Fees

§ 104.81 Limitation on Attorney Fees

(a) *In general.* (1) *In general.* Notwithstanding any contract, the representative of an individual may not charge, for services rendered in connection with the claim of an individual under this title, more than 10 percent of an award paid under this title on such claim.

(2) *Certification.* In the case of any claim in connection with which services covered by this section were rendered, the representative shall certify his or her compliance with this section and shall provide such information as the Special Master requires to ensure such compliance.

(b) *Limitation.* (1) *In general.* Except as provided in paragraph (b)(2) of this section, in the case of an individual who was charged a legal fee in connection with the settlement of a civil action described in section 405(c)(3)(C)(iii) of the Act, the representative who charged such legal fee may not charge that individual any amount for compensation for services rendered in connection with a claim filed under this title.

(2) *Exception.* If the legal fee charged in connection with the settlement of a civil action described in section 405(c)(3)(C)(iii) of the Act of an individual is less than 10 percent of the aggregate amount of compensation

awarded to such individual through such settlement, the representative who charged such legal fee to that individual may charge an amount for compensation for services rendered to the extent that such amount charged is not more than—

(i) Ten (10) percent of such aggregate amount through the settlement, minus

(ii) The total amount of all legal fees charged for services rendered in connection with such settlement.

(c) *Discretion to lower fee.* In the event that the Special Master finds that the fee limit set by paragraph (a) or (b) of this section provides excessive compensation for services rendered in connection with such claim, the Special Master may, in the discretion of the Special Master, award as reasonable compensation for services rendered an amount lesser than that permitted for in paragraph (a) of this section.

Dated: June 16, 2011.

Sheila L. Birnbaum,
Special Master.

[FR Doc. 2011-15459 Filed 6-20-11; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 906

[SATS No. CO-040-FOR, Docket ID: OSM-2011-0002]

Colorado Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We are announcing receipt of a proposed amendment to the Colorado regulatory program (hereinafter, the “Colorado program”) under the Surface Mining Control and Reclamation Act of 1977 (“SMCRA” or “the Act”). Colorado proposes both additions of and revisions to the rules and regulations of the Colorado Mined Land Reclamation Board for Coal Mining, concerning valid existing rights, ownership and control, and other regulatory issues. Colorado intends to revise its program to be consistent with the corresponding Federal regulations and SMCRA, clarify ambiguities, and improve operational efficiency.

This document gives the times and locations that the Colorado program and proposed amendment to that program are available for your inspection, the comment period during which you may

submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., mountain standard time July 21, 2011. If requested, we will hold a public hearing on the amendment on July 18, 2011. We will accept requests to speak until 4 p.m., mountain standard time, on July 6, 2011.

ADDRESSES: You may submit comments, identified by “CO-040-FOR”, using any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. The proposed rule has been assigned Docket ID OSM-2011-0002. If you would like to submit comments via the Federal eRulemaking portal, go to <http://www.regulations.gov> and follow the instructions.

- *Mail, Hand Delivery/Courier:* Kenneth Walker, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, CO 80202, Phone: (303) 293-5012, Fax: (303) 293-5058, E-mail: kwalker@osmre.gov.

Instructions: All submissions received must include the agency name and “CO-040-FOR.” For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Comment Procedures heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: Access to the docket to review copies of the Colorado program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, may be obtained at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting the Office of Surface Mining Reclamation and Enforcement’s (OSM’s) Denver Field Division. In addition, you may review a copy of the amendment during regular business hours at the following locations:

Kenneth Walker, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, CO 80202, Phone: (303) 293-5012, Fax: (303) 293-5058, E-mail: kwalker@osmre.gov.

David Berry, Director, Office of Mined Land Reclamation, Colorado Division of Reclamation, Mining, and Safety, Department of Natural Resources, 1313 Sherman Street, Suite 215, Denver, CO 80203, E-mail: David.Berry@state.co.us.

Or anytime at: <http://www.regulations.gov>, Docket ID OSM-2011-0002.

SUPPLEMENTARY INFORMATION:

- I. Background on the Colorado Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Colorado Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Colorado program on December 15, 1980. You can find background information on the Colorado program, including the Secretary’s findings, the disposition of comments, and the conditions of approval of the Colorado program in the December 15, 1980, **Federal Register** (45 FR 82173). You can also find later actions concerning Colorado’s program and program amendments at 30 CFR 906.10, 906.15, 906.16, and 906.30.

II. Description of the Proposed Amendment

By letter dated April 8, 2011, Colorado sent us a proposed amendment to its approved regulatory program (Administrative Record Docket ID No. OSM-2011-0002) under SMCRA (30 U.S.C. 1201 *et seq.*). Colorado submitted the amendment to address all required rule changes OSM identified by letters to Colorado dated April 4, 2008, and October 2, 2009, under 30 CFR 732.17(c). These included changes to Colorado’s rules for valid existing rights and ownership and control. The amendment also includes changes made at Colorado’s own initiative. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

Specifically, Colorado proposes substantive revisions to the Colorado Code of Regulations at 2 CCR 407-2 Rules 1.07 (Procedures for Valid Existing Rights Determinations), 2.01 (General Requirements for Permits), 2.02 (General Requirements for Coal Exploration), 2.03 (Application for Permit for Surface Coal Mining and Reclamation Operations: Minimum