

### 2. Paperwork Reduction Act

This rule does not impose an information collection burden under the Paperwork Reduction Act.

### 3. Regulatory Flexibility Act

After considering the economic impacts of this rule on small entities under the Regulatory Flexibility Act, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

### 4. Unfunded Mandates Reform Act

Because this rule approves preexisting requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act.

### 5. Executive Order 13132: Federalism

Executive Order 13132 does not apply to this rule because it will not have federalism implications (*i.e.*, substantial direct effects on the State, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government) as described in Executive Order 13132.

### 6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 does not apply to this rule because it will not have tribal implications (*i.e.*, substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes). As stated previously, this action would have no effect on the Indian country within the State's borders and EPA will continue to implement and administer the RCRA program in Indian country within the State.

### 7. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks

This rule is not subject to Executive Order 13045 because it is not economically significant and it is not based on health or safety risks.

### 8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211 because it is not a significant regulatory action as defined in Executive Order 12866.

### 9. National Technology Transfer Advancement Act

EPA approves State programs as long as they meet criteria required by RCRA, so it would be inconsistent with applicable law for EPA, in its review of a State program, to require the use of any particular voluntary consensus standard in place of another standard that meets the requirements of RCRA. Thus, Section 12(d) of the National Technology Transfer and Advance Act does not apply to this rule.

### 10. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

Because this rule addresses authorizing pre-existing State rules and imposes no additional requirements beyond those imposed by State law and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898.

### 11. Executive Order 12988

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct.

### 12. Executive Order 12630: Evaluation of Risk and Avoidance of Unanticipated Takings

EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings issued under the Executive Order.

### List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

**Authority:** This notice is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: September 8, 2011.

**Jared Blumenfeld,**

*Regional Administrator, Region 9.*

[FR Doc. 2011-25899 Filed 10-6-11; 8:45 am]

**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 110

RIN 0906-AA83

### Countermeasures Injury Compensation Program (CICP): Administrative Implementation, Final Rule

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Final rule; technical amendments.

**SUMMARY:** This document adopts the Countermeasures Injury Compensation Program Administrative Implementation Interim Final Rule as the final rule with technical amendments. The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to establish the Countermeasures Injury Compensation Program (CICP or Program). The Department of Health and Human Services (HHS) is issuing this final rule to adopt the administrative policies, procedures, and requirements for the CICP set out in the interim final rule, which was published and effective on October 15, 2010. This Program is designed to provide benefits to certain persons who sustain serious physical injuries or death as a direct result of administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as the direct result of such covered injuries or their health complications. The Secretary makes only minor technical amendments to the interim final rule, described below, and otherwise adopts the regulation as published on October 15, 2010.

**DATES:** This rule is effective October 7, 2011.

**FOR FURTHER INFORMATION CONTACT:** Dr. Vito Caserta, Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-06, 5600 Fishers Lane, Rockville, MD 20857. Phone calls can be directed to (855) 266-CICP (2427). This is a toll-free number.

### SUPPLEMENTARY INFORMATION:

#### Background

This regulation adopts the interim final rule that administratively established the compensation program

authorized by the Public Readiness and Emergency Preparedness Act (the PREP Act), which added new authorities under sections 319F-3 and 319F-4 of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 247d-6d, 247d-6e). The PREP Act, which was enacted as part of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006 (Pub. L. 109-148) on December 30, 2005, confers broad liability protections to covered persons and authorizes compensation to eligible individuals who sustain serious physical injuries or death as the direct result of the administration or use of a covered countermeasure for a disease, condition, or threat that the Secretary of Health and Human Services (the Secretary) determines either constitutes a current public health emergency or may in the future constitute such an emergency. This determination is identified in a declaration issued by the Secretary under the PREP Act.

Both the liability protections and the compensation authorized under the PREP Act are invoked by declarations issued by the Secretary (hereinafter PREP Act declarations or declarations) (section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(b)). Through the issuance of such PREP Act declarations, the Secretary makes a determination that a disease, condition, or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.

The Secretary publishes all PREP Act declarations, and amendments to such declarations, in the **Federal Register**. In addition, they are posted on the Department's Web site at <http://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx> and on the Countermeasures Injury Compensation Program's (hereinafter "CICP" or "Program") Web site at <http://www.hrsa.gov/countermeasurescomp/>. As of September 2011, the Secretary had published declarations with respect to the following countermeasures: (1) Pandemic influenza vaccines (including, but not limited to the influenza A H1N1 2009 monovalent vaccine which will be referred to hereafter as the 2009 H1N1 vaccine); (2) anthrax countermeasures; (3) botulism countermeasures; (4) the influenza antiviral drugs Tamiflu® and Relenza® when used for pandemic purposes; (5) smallpox countermeasures; (6) acute radiation syndrome countermeasures; (7) pandemic influenza diagnostics, personal respiratory devices, and

respiratory support devices; and (8) the influenza antiviral drug peramivir when used to treat pandemic H1N1 2009 influenza (which will be referred to hereafter as 2009 H1N1). Several of these declarations have been amended, some on multiple occasions.

In addition to establishing the PREP Act's liability protections for covered persons, the PREP Act authorized the Secretary to establish a program to provide compensation to eligible individuals for certain covered injuries sustained as the direct result of the administration or use of a covered countermeasure identified in a PREP Act declaration. The Secretary delegated the authority to operate the compensation program described in section 319F-4 of the PHS Act (42 U.S.C. 247d-6e) to the Administrator of the Health Resources and Services Administration (HRSA) on November 8, 2006. Pursuant to this delegation of authority, HRSA established and administers the CICP.

Under the CICP, certain persons may be eligible for benefits for covered injuries sustained as a direct result of the administration or use of covered countermeasures. The PREP Act stipulates that the CICP must follow, with very limited exceptions, the Smallpox Vaccine Injury Compensation Program (SVICP) for eligibility and compensation determinations (section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4)). In addition, the elements of compensation are almost identical to those available under the SVICP (section 319F-4(b)(2) of the PHS Act (42 U.S.C. 247d-6e(b)(2))). The SVICP was established under the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA) and its implementing regulations are available at 42 CFR part 102. Specifically, the PREP Act provides that (with limited exceptions) the CICP is to follow the SEPPA, the SVICP regulations implementing the SEPPA, and such additional or alternate regulations as the Secretary may promulgate for purposes of this section (section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4))). The Secretary is issuing this final rule under that authority.

On October 15, 2010, the Secretary published an interim final rule establishing the procedures and requirements governing the CICP. Although the interim final rule was effective on the date of publication, the Secretary sought public comments and indicated that she might amend the procedures and requirements described in the interim final rule based on the comments received. No public comments were received on the interim

final rule. On October 21, 2010, the Secretary published minor corrections to the interim final rule in the **Federal Register** (75 FR 64955).

As authorized under the PREP Act, the Secretary is herein adopting, as the final rule, the interim final rule that was effective on October 15, 2010 with minor technical amendments. Specifically, this final rule makes three amendments to the interim final rule to correct typographical errors and one amendment for purposes of clarification. First, the final rule amends section 110.3(f)(1) (included in the definition of a covered countermeasure) by replacing the reference to "§ 110.3(aa)" with "§ 110.3(bb)." Second, the final rule amends section 110.3(g) (which includes the definition of a covered injury) by replacing the reference to "§ 110.20(b)" (concerning covered injuries generally) with "§ 110.3(z)" (the definition of a serious injury). Both of these amendments are technical in nature and correct typographical errors. Third, the final rule amends section 110.42(f) (concerning deadlines for filing Request Forms based on the initial publication of a Table of Injuries or on modifications to an existing Table) by moving "within one year after the effective date of the establishment of, or amendment to, the Table" from the end of the sentence and inserting it at the beginning of the sentence, immediately following "In such circumstances,." This amendment also is technical in nature, and clarifies that, within one year of the effective date of the publication of a new Table or of an amendment to an existing Table, requesters who were previously denied eligibility for benefits must file a new Request Form, and requesters who did not previously file a Request Form must do so.

The Secretary is aware that the preamble to the interim final rule contained several errors in the cross-references to certain paragraphs and subparagraphs, similar to the first two amendments to the regulatory text described above. However, these errors were entirely typographical in nature and had no substantive implications, so they are not addressed here.

Additionally, the Secretary notes that, as permitted by the Privacy Act, the individuals administering the National Vaccine Injury Compensation Program (VICP) and the CICP for the Department may share records that are filed with either of the programs. For instance, the VICP and CICP may want to share medical records of an individual who applied to both programs.

### Justification for Waiver of Delayed Effective Date

The Secretary has found that a delay in the effective date of this final rule is unnecessary because the amendments made to the previous interim final rule are merely corrections of typographical errors and one clarification. Through the enactment of the PREP Act, the Secretary was authorized to establish and administer the Program. Congress authorized the Secretary to issue regulations implementing the PREP Act as the Secretary deems reasonable and necessary. In accordance with that statutory authority, the Secretary established the procedures and requirements to govern the Program, and published them as an interim final rule with a 60-day comment period. The Department received no public comments in response to the publication of the interim final rule on October 15, 2010 and with three minor exceptions, the text of the interim final rule is being adopted without change in this final rule. A delay in the effective date of this final rule, which adopts the interim final rule with only minor technical changes is unnecessary and contrary to the public interest. It is important for individuals requesting Program benefits to know that the procedures and requirements set out in the interim final rule remain unchanged.

### Economic and Regulatory Impact

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity and of available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are "significant" because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

In 2011, the President issued Executive Order 13563, which supplements and reaffirms Executive Order 12866. Executive Order 13563 provides that, to the extent feasible and permitted by law, the public shall be provided with a meaningful opportunity to comment through the Internet on any proposed regulations, with at least a 60-day comment period. In addition, to the extent feasible and permitted by law, agencies must provide timely on-line access to both proposed and final rules of the rulemaking docket on regulations.gov, including relevant scientific and technical findings, in an open format that can be searched and downloaded. Federal agencies must

consider approaches to maintain the freedom of choice and flexibility, including disclosure of relevant information to the public. Regulations must be guided by objective scientific evidence, easy to understand, consistent, and written in plain language. Furthermore, Federal agencies must attempt to coordinate, simplify, and harmonize regulations to reduce costs and promote certainty for the public. The interim final rule published on October 15, 2010 satisfied these requirements.

The Secretary has determined that minimal resources are required to implement the provisions included in this regulation. Therefore, in accordance with the Regulatory Flexibility Act (RFA) of 1980, and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this final rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. The Secretary has determined that this final rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801, and that this final rule also comports with the 2011 supplemental requirements of Executive Order 13563.

*Unfunded Mandates Reform Act of 1995:* The Secretary has determined that this final rule will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

*Federalism Impact Statement:* The Secretary has also reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the states, or on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government."

*Impact on Family Well-Being:* This final rule will not adversely affect the following elements of family well-being. Family safety, family stability, marital commitment; parental rights in the education, nurture and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of

1999. In fact, this final rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that injured persons, their families or survivors receive, or are helped by, medical, lost employment income, and/or death benefits paid under this part without imposing a corresponding burden on them.

*Impact of the New Rule:* In this final rule, the Secretary adopts the administrative procedures and requirements applicable to requesters filing for benefits under the Program, as established in the interim final rule. This final rule will have the effect of enabling certain eligible individuals who sustained covered injuries as the direct result of receiving a covered countermeasure under the Secretary's declaration, to receive benefits under the Program. In the event that an otherwise eligible injured countermeasure recipient has died, his or her estate and/or survivors may be entitled to certain benefits.

*Paperwork Reduction Act of 1995:* The information collection requirements remain unchanged.

### List of Subjects in 42 CFR Part 110

Benefits, Biologics, Compensation, Immunization, Public health, Pandemic, Countermeasures, Pandemic influenza, 2009 H1N1 vaccine, Influenza antivirals, Tamiflu®, Relenza®, Peramivir, Pandemic influenza diagnostics, Personal respiratory devices, N-95 filtering facepiece respirators, Respiratory support devices, Ventilators, Anthrax, Smallpox, Botulism, Acute radiation syndrome.

Dated: September 27, 2011.

### Mary Wakefield,

Administrator, Health Resources and Services Administration.

Approved: September 27, 2011.

### Kathleen Sebelius, Secretary.

For the reasons stated in the preamble, the Secretary adopts the interim final rule adding 42 CFR part 110, published at 75 FR 63656 on Friday, October 15, 2010, as a final rule with the following amendments:

### PART 110—COUNTERMEASURES INJURY COMPENSATION PROGRAM

■ 1. The authority section for part 110 continues to read as follows:

**Authority:** 42 U.S.C. 247d-6e.

■ 2. Amend § 110.3 by revising paragraphs (f) introductory text, (f)(1) and (g) introductory text to read as follows:

**§ 110.3 Definitions.**

\* \* \* \* \*

(f) *Covered Countermeasure* means the term that is defined in section 319F-3(i)(1) of the PHS Act and described in a declaration issued under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(i)(I), (b)). To be a covered countermeasure for purposes of this part, the countermeasure must have been administered or used pursuant to the terms of a declaration, or in a good faith belief of such; and

(1) Administered or used within a State (as defined in § 110.3(bb)), or otherwise in the territory of the United States; or

\* \* \* \* \*

(g) *Covered Injury* means death, or a serious injury as described in § 110.3(z), and determined by the Secretary in accordance with § 110.20 of this part to be:

\* \* \* \* \*

■ 3. Amend § 110.42 by revising paragraph (f) to read as follows:

**§ 110.42 Deadlines for filing Request Forms.**

\* \* \* \* \*

(f) *Request Forms (or amendments to Request Forms) based on initial publication of a Table of Injuries or modifications to an existing Table.* The Secretary may publish a new Table (or Tables) by amendment(s) to subpart K of this part. The effect of such a new Table or amendment may enable a requester who previously could not establish a Table injury to do so. In such circumstances, within one year after the effective date of the establishment of, or amendment to, the Table, the requester must file a new Request Form if one was previously submitted and eligibility was denied or if one was not previously submitted. If the Secretary has not made a determination, she will automatically review any pending Request Forms in light of the new or amended Table(s).

\* \* \* \* \*

[FR Doc. 2011-25858 Filed 10-6-11; 8:45 am]

BILLING CODE 4165-15-P

**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Chapter I**

[PS Docket No. 06-229; WT Docket 06-150; WP Docket 07-100; FCC 11-113]

**Implementing a Nationwide, Broadband, Interoperable Public Safety Network in the 700 MHz Band**

AGENCY: Federal Communications Commission.

ACTION: Final rule.

**SUMMARY:** In this document, the Commission considered a request for declaratory ruling filed by the City of Charlotte, North Carolina, seeking guidance on the scope of permissible operations under section 337 of the Communications Act as undertaken by state, local and other governmental entities in the public safety broadband spectrum of the 700 MHz band. The Commission dismissed the request, but clarified that a reasonably broad interpretation of the definition of “public safety services” under section 337 of the Act would allow some of the uses proposed by Charlotte and other commenters.

DATES: Effective October 7, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Jennifer Manner, Federal Communications Commission, Public Safety and Homeland Security Bureau, 445 12th Street, SW., Room 7-C761, Washington, DC 20554. Telephone: (202)-418-3619, e-mail: [jennifer.manner@fcc.gov](mailto:jennifer.manner@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission’s *Fourth Report and Order*, FCC 11-113, adopted July 20, 2011, and released July 21, 2011. The *Fourth Report and Order* is available at [http://transition.fcc.gov/Daily\\_Releases/Daily\\_Business/2011/db0721/FCC-11-113A1.pdf](http://transition.fcc.gov/Daily_Releases/Daily_Business/2011/db0721/FCC-11-113A1.pdf).

**Summary of Fourth Report and Order**

The Commission considered a request for declaratory ruling filed by the City of Charlotte, North Carolina (Charlotte), requesting that the Commission clarify that “[t]erritories, possessions, states, counties, towns or similar State or local governmental entities that qualify as 700 MHz lessees/users have as their sole or principal purpose the protection of the safety of life, health and property and are permitted to use 700 MHz broadband spectrum for activities conducted by their personnel including, but not limited to, activities of police, fire and medical emergency first responders.” The Commission determined that the plain language of section 337 of the Communications Act does not support this broad presumption, and it accordingly dismissed Charlotte’s request. The Commission clarified, however, that there is sufficient flexibility within section 337 to encompass many of the state and local government uses of the spectrum contemplated by Charlotte and by other commenters.

**Regulatory Flexibility Act**

This *Fourth Report and Order* does not promulgate any “rule” as that term is defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2) *et. seq.*, so the Commission is not required to prepare a Final Regulatory Flexibility Analysis at this stage of this proceeding.

**Paperwork Reduction Act Analysis**

The *Fourth Report and Order* contains no new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. The Commission shall send a copy of the *Fourth Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2011-26023 Filed 10-6-11; 8:45 am]

BILLING CODE 6712-01-P

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 001005281-0369-02]

RIN 0648-XA753

**Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

**SUMMARY:** NMFS closes the northern Florida west coast subzone to the commercial harvest of king mackerel in or from the exclusive economic zone (EEZ). This closure is necessary to protect the Gulf king mackerel resource.

**DATES:** This rule is effective 12:01 a.m., local time, October 7, 2011, until 12:01 a.m., local time, July 1, 2012, unless changed by further notice in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Susan Gerhart, telephone: 727-824-5305, or e-mail: [susan.gerhart@noaa.gov](mailto:susan.gerhart@noaa.gov).

**SUPPLEMENTARY INFORMATION:** The fishery for coastal migratory pelagic fish