

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

RIN 0905-AA68

National Vaccine Injury Compensation Program: Calculation of Average Cost of a Health Insurance Policy

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

ACTION: Notice of proposed rulemaking.

SUMMARY: Subtitle 2 of Title XXI of the Public Health Service Act, as enacted by the National Childhood Vaccine Injury Act of 1986, as amended (the Act), governs the National Vaccine Injury Compensation Program (VICP). The VICP, administered by the Secretary of Health and Human Services (the Secretary), provides that a proceeding for compensation for a vaccine-related injury or death shall be initiated by service upon the Secretary, and the filing of a petition with the United States Court of Federal Claims (the Court). In some cases, the injured individual may receive compensation for future lost earnings, less appropriate taxes and the "average cost of a health insurance policy, as determined by the Secretary." The Secretary now proposes a new method of calculating the average cost of a health insurance policy.

DATES: Comments must be submitted by August 8, 2006. Subject to consideration of the comments submitted, the Secretary intends to publish final regulations.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0905-AD25, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- E-mail: gevens@hrsa.gov. Include RIN 0905-AD25 in the subject line of the message.
- Mail: Geoffrey Evans, M.D., Director, Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), Room 11C-26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All comments received will be available for public inspection and copying without charge, including any personal information provided, at Parklawn Building, 5600

Fishers Lane Room 11C-26, Rockville, Maryland 20857, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT:

Geoffrey Evans, M.D. at the mail or e-mail address above or by telephone at (301) 443-6593.

SUPPLEMENTARY INFORMATION: Under the Act, an individual may file a petition with the Court for compensation for a vaccine-related injury or death. The Secretary is named by the Act as the Respondent in these proceedings and carries out other functions under the Act. The Secretary's authorities under the VICP established by the Act have been delegated to the HRSA.

The elements of compensation that may be awarded to a successful petitioner are set out in Section 2115 of the Public Health Service (PHS) Act, 42 U.S.C. 300aa-15. Subsection (a)(3)(B) specifically provides for compensation for lost earnings for a person who has sustained a vaccine-related injury before attaining the age of 18, and whose earning capacity is or has been impaired sufficiently to anticipate that such person is likely to suffer impaired earning capacity at age 18 and beyond. The injured person would be eligible to receive compensation for lost earnings, after the age of 18, which are calculated on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the " * * * average cost of a health insurance policy, as determined by the Secretary." The wage data are taken from the Employment and Earnings survey done by the Department of Labor, Bureau of Labor Statistics (BLS). (Subsection (a)(3)(A) specifically provides for payment of actual and anticipated lost earnings for individuals injured after reaching age 18 and does not include deductions for taxes and the cost of health insurance.)

The Department of Health and Human Services (HHS) is proposing to revise the current methodology for calculating the average cost of a health insurance policy, which is an amount deducted from the award of compensation in certain cases. Due to the availability of an improved data source, the current methodology should be changed because the proposed methodology will yield a more accurate calculation of the average cost of a health insurance policy.

Currently, the methodology uses a baseline of \$141.00, which was the average monthly premium cost for individuals covered under employment related group insurance in 1990 according to the 1990 Employer Health

Benefits survey conducted by the Health Insurance Association of America (HIAA). This baseline of \$141.00 has been increased by the increase in the medical care component of the Consumer Price Index (CPI)—All Urban Consumers, U.S. City Average, which is published by the BLS, plus a 2 percent per year increase. The medical care component of the CPI has been used because it was the only Federal Government survey available at the time which reflected average changes in the costs of health insurance. The two percent is added to account for technological advances in and higher utilization of health care. From time to time, the Secretary has published notices in the **Federal Register** with updated amounts which reflect the average monthly cost of a health insurance policy, as calculated above.

The medical care component of the CPI consists of the changes in the costs of medical care (e.g. non-prescription drugs and medical supplies), not just changes in the cost of health insurance. Furthermore, it only tracks the changes in the costs of health insurance, not the actual cost of a health insurance policy. Therefore, the Secretary is proposing a new methodology to calculate the average cost of a health insurance policy. The proposed methodology uses the Medical Expenditure Panel Survey—Insurance Component (MEPS-IC) data to periodically determine the baseline for calculating the average cost of a health insurance policy because it is the only national annual survey solely estimating health insurance costs among various populations that is conducted by a Federal Government agency. The MEPS-IC is conducted annually by the Agency for Healthcare Research and Quality (AHRQ), an agency within HHS. The MEPS-IC began in 1997 with data collected for calendar year 1996. It has the largest sample size of the national surveys used to estimate health insurance costs. The number of respondents ranges from 30,000 to 40,000 annually. For more information about MEPS-IC, call the Project Director, Center for Cost and Financing Studies, Medical Expenditure Panel Survey, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850; telephone (301) 427-1406, e-mail: mepsd@ahrq.gov, or visit the MEPS Web site at: <http://www.ahrq.gov/data/mepsix.htm>.

The Secretary proposes to obtain a new baseline periodically (generally on an annual basis) from the average total single premium per enrolled employee at private-sector establishments that offer health insurance, as reported by

the most recent MEPS-IC data. Because MEPS-IC data are collected retrospectively, there is a time lag between when the data are collected and when they are reported. Currently, this is a 2-year time lag. Therefore, the Secretary proposes increasing or decreasing the most recent MEPS-IC baseline by the annual percentage change(s) in the average monthly premium costs for covered single workers from the most recent Kaiser Family Foundation and Health Research and Educational Trust (KFF/HRET) annual survey, "Employer Health Benefits" or other authoritative sources that may be more accurate or appropriate in the future. If another authoritative source is used, the Secretary will publish a notice in the **Federal Register** announcing this change.

Since 1999, the KFF/HRET, independent non-profit organizations, have conducted the "Employer Health Benefits" survey. This survey collects prospective data from about 3,000 randomly selected public and private employers on the cost of health insurance benefits per employee per employer and combines the data for public and private employers. Data are collected based on the anticipated cost of a health insurance policy, not necessarily the actual cost because the data are collected prospectively. For more information about this survey, visit the KFF/HRET Web site at <http://www.kff.org/insurance/index.cfm>.

Using the KFF/HRET percentage change(s) to modify the baseline number would make the calculation of the average cost of a health insurance policy current, and would produce an accurate deduction from the compensation award. We note that the KFF/HRET survey data are reported the same year in which they are collected, and tend to have comparable annual percentage increases or decreases to the subsequent MEPS-IC data for the same years as detailed in the table in the Economic and Regulatory Impact Section of this NPRM. The annual percentage change as reported by the KFF/HRET survey provides a more accurate modifier than the addition of the medical care component of the CPI plus 2 percent, as has been used under the current regulation because the medical care component of the CPI consists of the changes in the costs of medical care (e.g. non-prescription drugs, medical supplies, health insurance), not the actual cost of a health insurance policy.

Given the current 2-year time lag, the calculation for 2005 would be as follows. In August 2005, MEPS-IC published the annual 2003 average total

single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$3,481. This figure is divided by 12 months to determine the cost per month of \$290.08 which is the proposed new baseline figure for 2003. The Secretary proposes that the baseline of \$290.08 be increased or decreased by the percentage change reported by the most recent KFF/HRET survey. The percentage increase from 2003-2004 was 11.2 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy in 2004 is \$322.57. The KFF/HRET reported increase from 2004-2005 was 9.2 percent. By adding this percentage increase to the calculated \$322.57 for 2004, the calculated average monthly cost of a health insurance policy in 2005 would be \$352.25. Under the current methodology, the calculated average monthly cost of a health insurance policy would be \$374.82. If the revised calculation of the new baseline is published in the **Federal Register** in final form using this new methodology, the Secretary will include in the Final Rule the latest calculation of the average cost of a health insurance policy using the new methodology.

Since the KFF/HRET survey is published annually, the Department will periodically (generally on an annual basis) recalculate the average cost of a health insurance policy by obtaining a new baseline from the latest MEPS-IC data and updating this baseline using the percentage change(s) reported by the most recent data from KFF/HRET or other authoritative source that may be more accurate or appropriate in the future. The updated calculation will be published as a notice in the **Federal Register** and filed with the Court.

This proposed methodology will result in a more accurate reflection of the actual average cost of a health insurance policy as compared to the figure reached under the current methodology. Because the amount of compensation for lost wages is reduced by this figure for some petitioners receiving compensation under the VICP, such petitioners will receive a more accurate amount of compensation if the proposed methodology is adopted.

The reduction in the compensation is done once and that is at the time the award is made. It is based on the average cost of a health insurance policy at that point in time. No further reductions are made because of increases in the cost of a health insurance policy.

This proposed methodology will only apply to the determination of lost wages after the effective date of the Final Rule. Awards already made before this date will not be recalculated.

Economic and Regulatory Impact

Regulatory Flexibility Act and Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety distributive and equity effects). In addition, under the Regulatory Flexibility Act of 1980 (RFA), if a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule. 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 the Secretary's view, the amendment proposed in this notice would require minimal resources to implement, if any. Therefore, in accordance with the RFA, and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that the amendment proposed by this rule will not affect any entities defined as small under this Act and will not have a significant impact on a substantial number of small entities.

The change proposed here 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 the proposed rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. The Secretary conducted a cost analysis of the current versus the proposed methodology. The difference in using the current vs. proposed methodologies was calculated for a single claim. This difference was multiplied by the annual average percent of claims compensated that include this calculation (20

percent). The proposed methodology is estimated to increase the annual total amount of awards by \$50,000. Therefore, the additional cost to the

Federal government will be about \$50,000 per year. The table below compares the average cost of a health insurance policy using

MEPS-IC only, KFF/HRET only and the proposed methodology.

Year	KFF/HRET only	MEPS-IC only	Proposed methodology
2000	\$202	\$221.22	¹ \$206.44
2001	221	240.77	² 232.46
2002	255	265.75	³ 276.98
2003	282	290.08	⁴ 309.61
2004	308	N/A	⁵ 336.59
2005	335	N/A	⁶ 352.25

N/A—Not available due to 2-year lag in reporting data.
¹ 1998 MEPS-IC increased by 1999 and 2000 percent changes from KFF/HRET.
² 1999 MEPS-IC increased by 2000 and 2001 percent changes from KFF/HRET.
³ 2000 MEPS-IC increased by 2001 and 2002 percent changes from KFF/HRET.
⁴ 2001 MEPS-IC increased by 2002 and 2003 percent changes from KFF/HRET.
⁵ 2002 MEPS-IC increased by 2003 and 2004 percent changes from KFF/HRET.
⁶ 2003 MEPS-IC increased by 2004 and 2005 percent changes from KFF/HRET.

The table below shows a comparison of the average cost of a health insurance policy using the current and proposed methodologies, and the percent change between these methodologies.

Year	Current methodology	Proposed methodology	Percent change (current vs. proposed)
2000	\$276.28	\$206.44	-21
2001	294.24	232.46	-21
2002	313.78	276.98	-12
2003	332.60	309.61	-7
2004	353.81	336.59	-5
2005	374.82	352.25	-6

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Unfunded Mandates Reform Act of 1995

The Secretary has determined that the amendment proposed in this notice would 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 proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The proposed rule would 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 proposed 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.

Impact of the New Rule

If the amendment proposed in this notice is adopted, § 100.2 will be revised to incorporate a new methodology for calculating the average cost of a health insurance policy. As explained in this notice, we expect this new methodology to result in a more accurate reflection of the actual average cost of a health insurance policy as compared to the figure reached under the methodology that is currently used which resulted in a number that was too high in the past.

Paperwork Reduction Act of 1980

This proposed rule has no information collection requirements.

List of Subjects

Biologics, Compensation, Health insurance, Immunizations.

Dated: May 25, 2006.

Elizabeth M. Duke,
Administrator, HRSA.

Approved: February 28, 2006.

Michael O. Leavitt,
Secretary.

For the reasons stated above, HHS proposes to amend part 100 of 42 CFR as follows:

PART 100—VACCINE INJURY COMPENSATION

1. The authority section for 42 CFR part 100 is revised to read as follows:

Authority: Secs. 312 and 313 of Pub. L. 99-660, 100 Stat. 3779-3782 (42 U.S.C. 300aa-1 note); sec. 2114(c) and (e) of the PHS Act (42 U.S.C. 300aa-14(c) and (e)); sec. 2115(a)(3)(B) of the PHS Act (42 U.S.C. 300aa-15(a)(3)(B)); sec. 904(b) of Pub. L. 105-34, 111 Stat. 873; sec. 1503 of Pub. L. 105-277, 112 Stat. 2681-741; and sec. 523(a) of Pub. L. 106-170, 113 Stat. 1927-1928.

2. Section 100.2 is revised to read as follows:

§ 100.2 Average cost of a health insurance policy.

For purposes of determining the amount of compensation under the VICP, section 2115(a)(3)(B) of the PHS

Act, 42 U.S.C. 300aa-15(a)(3)(B), provides that certain individuals are entitled to receive an amount reflecting lost earnings, less certain deductions. One of the deductions is the average cost of a health insurance policy, as determined by the Secretary. The Secretary has determined that the average cost of a health insurance policy is \$352.25 for 2005. This figure is calculated periodically (generally on an annual basis) using the most recent Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation and Health Research and Educational Trust (KFF/HRET) Employer Health Benefits survey or other authoritative source that may be more accurate or appropriate in the future. The revised amount will be effective upon its delivery by the Secretary to the United States Court of Federal Claims, and the amount will be published as a notice in the **Federal Register** periodically (generally on an annual basis).

[FR Doc. E6-8992 Filed 6-8-06; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 060525140-6140-01; I.D. 051106B]

RIN 0648-AT75

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery Off the Southern Atlantic States; Amendment 13C

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS issues this proposed rule to implement Amendment 13C to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP), as prepared and submitted by the South Atlantic Fishery Management Council (Council). Amendment 13C proposes management measures to end overfishing of snowy grouper, golden tilefish, vermilion snapper, and black sea bass and

measures to allow moderate increases in recreational and commercial harvest of red porgy consistent with the rebuilding program for that stock.

For the commercial fisheries, this proposed rule would establish restrictive quotas for snowy grouper, golden tilefish, vermilion snapper, and black sea bass and, after the quotas are met, prohibit all purchase and sale of the applicable species and restrict all harvest and possession to the applicable bag limit; establish restrictive trip limits for snowy grouper and golden tilefish; require at least 2-inch (5.1-cm) mesh in the back panel of black sea bass pots; require black sea bass pots to be removed from the water after the quota is reached; change the fishing year for black sea bass; increase the trip limit for red porgy; establish a red porgy quota that would allow a moderate increase in harvest; and, after the red porgy quota is reached, prohibit all purchase and sale and restrict all harvest and possession to the bag limit.

For the recreational fisheries, this proposed rule would reduce the bag limits for snowy grouper, golden tilefish, and black sea bass; increase the minimum size limit for vermilion snapper and black sea bass; change the fishing year for black sea bass; and increase the bag limit for red porgy.

The intended effects of this proposed rule are to eliminate or phase out overfishing of snowy grouper, golden tilefish, vermilion snapper, and black sea bass; and increase red porgy harvest consistent with an updated stock assessment and rebuilding plan to achieve optimum yield.

DATES: Written comments on this proposed rule must be received no later than 5 p.m., eastern time, on July 24, 2006.

ADDRESSES: You may submit comments on the proposed rule by any of the following methods:

- E-mail: 0648-

AT75.Proposed@noaa.gov. Include in the subject line of the e-mail comment the following document identifier: 0648-AT75.

- Federal e-Rulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Mail: John McGovern, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

- Fax: 727-824-5308; Attention: John McGovern.

Copies of Amendment 13C may be obtained from the South Atlantic Fishery Management Council, One Southpark Circle, Suite 306, Charleston, SC 29407-4699; phone: 843-571-4366 or 866-SAFMC-10 (toll free); fax: 843-

769-4520; e-mail: safmc@safmc.net. Amendment 13C includes a Final Environmental Impact Statement (FEIS), a Biological Assessment, an Initial Regulatory Flexibility Analysis (IRFA), a Regulatory Impact Review, and a Social Impact Assessment/Fishery Impact Statement.

Comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted in writing to Jason Rueter at the Southeast Regional Office address above and to David Rostker, Office of Management and Budget (OMB), by e-mail at David_Rostker@omb.eop.gov, or by fax to 202-395-7285.

FOR FURTHER INFORMATION CONTACT: John McGovern, telephone: 727-824-5305; fax: 727-824-5308; e-mail: John.McGovern@noaa.gov.

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery off the southern Atlantic states is managed under the FMP. The FMP was prepared by the Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. NMFS issues this proposed rule to implement Amendment 13C to the FMP.

Background

Recent stock assessments indicate that snowy grouper, golden tilefish, vermilion snapper, and black sea bass are experiencing overfishing. Overfishing means that the current rate of fishing mortality jeopardizes the capacity of the fishery for a species to produce its maximum sustainable yield on a continuing basis. Reductions in catch are needed to end overfishing.

Red porgy, however, are no longer experiencing overfishing, and the stock is rebuilding. Accordingly, catch can be increased to meet the annual allowable biological catch established in the rebuilding program for this species.

Provisions of This Proposed Rule

(Note that all poundages in this proposed rule are expressed in terms of gutted weight.)

Snowy Grouper

In the commercial fishery for snowy grouper, this proposed rule would:

Reduce, over a 3-year period, the commercial quota from 344,508 lb (156,266 kg), gutted weight, to 84,000 lb (38,102 kg), gutted weight. The quota would be reduced from 344,508 lb (156,266 kg) to 151,000 lb (68,492 kg) for year 1; to 118,000 lb (53,524 kg) for year 2; and to 84,000 lb (38,102 kg) for