

DELEGATION STATUS FOR PART 63 STANDARDS—STATE OF LOUISIANA¹—Continued

Subpart	Source category	LDEQ ^{2,3}
GGGG	Solvent Extraction for Vegetable Oil Production	X
HHHH	Wet Formed Fiberglass Mat Production	X
JJJJ	Paper and other Web (Surface Coating).	
NNNN	Surface Coating of Large Appliances.	
OOOO	Fabric Printing Coating and Dyeing.	
QQQQ	Surface Coating of Wood Building Products.	
RRRR	Surface Coating of Metal Furniture.	
SSSS	Surface Coating for Metal Coil	X
TTTT	Leather Finishing Operations	X
UUUU	Cellulose Production Manufacture	X
VVVV	Boat Manufacturing	X
WWWW	Reinforced Plastic Composites Production.	
XXXX	Tire Manufacturing.	
BBBBB	Semiconductor Manufacturing.	
CCCCC	Coke Ovens: Pushing, Quenching and Battery Stacks	X
FFFFF	Integrated Iron and Steel.	
JJJJJ	Brick and Structural Clay Products Manufacturing.	
KKKKK	Clay Ceramics Manufacturing.	
LLLLL	Asphalt Roofing and Processing.	
MMMMM	Flexible Polyurethane Foam Fabrication Operation.	
NNNNN	Hydrochloric Acid Production, Fumed Silica Production.	
PPPPP	Engine Test Facilities.	
QQQQQ	Friction Products Manufacturing.	
SSSSS	Refractory Products Manufacture.	

¹ Program delegated to Louisiana Department of Environmental Quality (LDEQ).

² Authorities which may not be delegated include: § 63.6(g), Approval of Alternative Non-Opacity Emission Standards; § 63.6(h)(9), Approval of Alternative Opacity Standards; § 63.7(e)(2)(ii) and (f), Approval of Major Alternatives to Test Methods; § 63.8(f), Approval of Major Alternatives to Monitoring; § 63.10(f), Approval of Major Alternatives to Recordkeeping and Reporting; and all authorities identified in the subparts (e.g., under "Delegation of Authority") that cannot be delegated.

³ Federal rules adopted unchanged as of July 1, 2002.

(ii) Affected sources within Louisiana shall comply with the Federal requirements of 40 CFR part 63—subpart S—Pulp and Paper Industry, adopted by reference by the Louisiana Department of Environmental Quality's (LDEQ), with the exception of the compliance date listed in § 63.440(d)(1). The LDEQ has adopted an earlier compliance date than the Federal requirement. The earlier compliance date is approved by EPA pursuant to § 63.92. Affected sources in Louisiana that are subject to the requirements of Subpart S shall meet the compliance date established at Louisiana Administrative Code, Title 33, part III, chapter 51, subchapter C., section 5122, C.2.

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[FR Doc. 04-6299 Filed 3-25-04; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 148

[CMS-2179-F]

RIN 0938-AM42

Grants to States for Operation of Qualified High Risk Pools

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: This final rule implements a provision of the Trade Adjustment Assistance Reform Act of 2002 by providing \$40 million in Federal fiscal year 2003 and \$40 million in Federal fiscal year 2004 to States that have incurred losses in connection with the operation of qualified high risk pools that meet certain criteria. This final rule also addresses comments received in response to the interim final rule that was published on May 2, 2003. This grant program implements section 2745 of the Public Health Service Act, as added by the Trade Adjustment Assistance Reform Act of 2002.

DATES: Effective date. These regulations are effective on April 26, 2004

Deadline for States to submit an application for losses incurred in their

fiscal year 2002: States had to submit an application to us by no later than September 30, 2003. Deadline for States to submit an application for losses incurred in their fiscal year 2003: States must submit an application to us by no later than June 30, 2004. Deadline for States to submit an application for losses incurred in their fiscal year 2004: States must submit an application to us by no later than June 30, 2005.

ADDRESSES: *Where To Submit an Application.* All initial applications and supplemental applications must be submitted to: Centers for Medicare & Medicaid Services, Acquisition and Grants Group, Mail Stop C2-21-15, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Nicole Nicholson.
FOR FURTHER INFORMATION CONTACT: James Mayhew, (410) 786-9244.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Section 2745(b) of the Public Health Service Act (PHS Act), as added by section 201(b) of the Trade Adjustment Assistance Reform Act of 2002, authorizes the Secretary to make grants to States for up to 50 percent of the losses they incur in the operation of qualified high risk pools, and appropriates the necessary funds. In order to qualify for a grant, a State's risk

pool must meet the definition of a qualified risk pool, as described in section II of this preamble, as well as other applicable eligibility requirements described in that section.

B. Availability and Use of Funds

The total amount appropriated for these grants is \$80 million (\$40 million each in Federal fiscal years (FYs) 2003 and 2004). We have 2 years to obligate funding for each fiscal year. As directed by the statute, we will allocate funds in accordance with a formula based upon the number of uninsured individuals in each eligible State. This formula, described in section II of this preamble and in 45 CFR 148.312(b) of this final rule, was developed using the most accurate and current statistics available on the uninsured in each State. Eligible States may apply for grants for amounts up to 50 percent of losses they incur in connection with the operation of a qualified high risk pool. A State must have a qualified high risk pool that has incurred a loss in order to be eligible for a grant.

C. The Final Rule With Comment Period

On May 2, 2003, we published a final rule with comment period (68 FR 23410) to benefit eligible States and uninsured populations. We made funds available as quickly as possible to eligible States to fund losses incurred in the operation of qualified high risk pools.

II. Provisions of the Final Rule with Comment Period Published on May 2, 2003 (63 FR 23410)

In the May 2, 2003 final rule with comment period, we added a new subpart E to 45 CFR part 148, to provide for grants to States that incur losses in connection with operating qualified high risk pools. This subpart implemented section 2745 of the PHS Act. Its purpose is to provide grants to States that have qualified high risk pools that meet the specific requirements described in § 148.310. It also provides specific instructions on how to apply for the grants and outlines the grant review and grant award processes.

In the May 2, 2003 final rule with comment period, we added § 148.306, which describes the statutory basis and scope of the regulation. We also added § 148.308, "Definitions." CMS stands for Centers for Medicare & Medicaid Services. For the purposes of subpart E, a "qualified high risk pool" is a high risk pool that meets the conditions described in § 148.128(a)(2)(ii): (1) It provides to all eligible individuals, as defined in § 148.103, health insurance

coverage (or comparable coverage) that does not impose any preexisting condition exclusion or affiliation periods for coverage of an eligible individual; and (2) provides for premium rates and covered benefits for the coverage consistent with the standards included in the National Association of Insurance Commissioners (NAIC) Model Health Plan for Uninsurable Individuals Act (as in effect as of August 21, 1996) but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

A "loss" means the difference between expenses incurred by a qualified high risk pool, including payment of claims and administrative expenses, and premiums collected by the pool. A "standard risk rate" means a rate developed by a State using reasonable actuarial techniques and taking into account the premium rates charged by the other insurers offering health insurance coverage to individuals in the same geographical service area to which the rate applies. The standard rate may be adjusted based upon age, sex, and geographical location.

In the May 2, 2003 final rule with comment period, we added § 148.310, which describes eligibility requirements for a grant. A State must meet all of the following requirements to be eligible for a grant:

(a) The State has a qualified high risk pool as defined in § 148.308.

(b) The pool restricts premiums charged under the pool to no more than 150 percent of the premium for applicable standard risk rates for the State.

(c) The pool offers a choice of two or more coverage options through the pool.

(d) The pool has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State after the end of fiscal year 2004 in connection with the operation of the pool.

(e) The pool has incurred a loss in a period described in § 148.314.

In the May 2, 2003 final rule with comment period, we added § 148.312, which describes the amount of a grant payment. Paragraph (a) provides that an eligible State may receive a grant to fund up to 50 percent of the losses incurred in the operation of its qualified high risk pool during the period for which it is applying. Paragraph (b) provides that we will allocate funds to each eligible State in accordance with the following formula:

(1) The number of uninsured individuals is calculated for each eligible State by taking a 3-year average

of the number of uninsured individuals in that State in the Current Population Survey (CPS) of the Census Bureau. For grants based upon State fiscal years 2002 and 2003, a 3-year average will be calculated using numbers available as of May 1, 2003. For grants based upon State fiscal year 2004, a 3-year average will be calculated using numbers available as of March 1, 2005. Calculation of the State 3-year average will be done by the Census Bureau and provided to CMS.

(2) Based upon the CPS numbers, the State's percentage of the total uninsured population of eligible States is calculated and then multiplied by \$40 million to determine the State's maximum allotment for the fiscal year in question. For example, if the most current 3-year average of uninsured individuals in State A is 1 million, and the 3-year average of uninsured individuals for all eligible States was 10 million, State A would have 10 percent of the uninsured population of the eligible States. Accordingly, State A's allotment would be 10 percent of \$40 million, or \$4 million, for the fiscal year in question.

Paragraph (c) states that the amount awarded to each eligible State will be the lesser of the 50 percent of losses incurred by its qualified risk pool for the fiscal year in question or its allotment under the formula.

In the May 2, 2003 final rule with comment period, we added § 148.314, which describes the periods for which eligible States may apply for grants; application deadlines; and allocation methodology. Under paragraph (a), an eligible State may apply for a grant to fund losses incurred in the operation of its qualified risk pool during the State's fiscal year 2002, 2003, or 2004. A State may apply for losses incurred in a partial fiscal year if a partial year audit is done. Under paragraph (b), an eligible State may only be awarded a maximum of two grants, with one grant per fiscal year. A grant for a partial fiscal year counts as a full grant. We also explain how we determine which grants will be funded out of which Federal fiscal year funds. This will depend in part on when the State submits its initial application.

In paragraph (c), we indicate that the deadlines for submitting grant applications are stated in § 148.316(d).

In paragraph (d), we explain how Federal funds will be distributed to States that may qualify at different points in time. The first group of States are those that submit applications for their fiscal year 2002 losses. (We will refer to those States as "02 States.") These States, that meet all the eligibility requirements and incur losses in

connection with a qualified high risk pool in State fiscal year 2002, had to submit a grant request by September 30, 2003. The first year grant for these States was funded with Federal fiscal year 2003 funds. The 02 States may be eligible for a second grant to fund their fiscal year 2003 losses. The deadline for those grant requests will be June 30, 2004. As explained below, these grants will be funded with Federal fiscal year 2004 funds. (If a State does not receive a grant for State fiscal year 2003, however, it still might qualify for its fiscal year 2004, as discussed below.)

The second group of States are those that did not submit applications for their 2002 fiscal years (or submitted applications but did not qualify) and that first qualify with respect to losses incurred in their fiscal year 2003. (We will refer to these States as "03 States.") These States may submit a grant request, which must be received by June 30, 2004. The first year grant for these States will be funded with Federal fiscal year 2003 funds. The 03 States (or any 02 States that did not apply or receive approval for losses incurred during State fiscal year 2003) may be eligible for a second grant to fund their fiscal year 2004 losses. The deadline for those grant requests will be June 30, 2005. Those grants will be funded with Federal fiscal year 2004 funds.

The third group of States are those that first qualify with respect to losses incurred in their fiscal year 2004. (We will refer to these States as "04 States.") These States may submit a grant request, which must be received by June 30, 2005. The first year grant for these States will be funded with Federal fiscal year 2004 funds. The 04 States will not be eligible for a second grant because the availability of Federal funds will have expired.

In paragraph (e), we explain how excess funds will be redistributed. The initial grants to the 02 States and the 03 States will come from the Federal fiscal year 2003 funds. After the deadline for 02 grants, we will determine how many States have submitted applications for grants. We will estimate, based upon contacts with other States that have shown interest, how many requests are likely to be received from 03 States. We will make an initial allotment for 02 States based upon these estimates. In other words, we will reserve some of the Federal fiscal year 2003 funds after the 02 States grant requests have been received in anticipation of requests being made by 03 States. Based upon expressions of interest we have received from States, we believe we have a reasonable estimate of the States that are likely to first qualify in their fiscal year

2003. We will hold in reserve our best estimate of the maximum amount of funds needed to provide full allotments to these States. If there are excess reserves (that is, the Department withholds more money than was necessary to provide grants to the 03 States), the excess funds will be proportionally redistributed to the 02 States and the 03 States, not to exceed 50 percent of losses incurred by the States. In other words, the size of the first year grants will be increased retroactively for these States.

In the unlikely event that the Department should underestimate the reserve needed to fund grants to all eligible 03 States, money will be taken from the Federal fiscal year 2004 funds to ensure that all eligible 03 States receive grants on an equivalent basis. We do not expect it to have a major impact on funding of the additional grants from the Federal fiscal year 2004 funds. Similarly, the Department will reserve some of the Federal fiscal year 2004 money to fund the second year grants for 02 and 03 States and the first year grants for the 04 States.

We believe that this method of distribution of the Federal funds is the fairest because it allows for States that qualified for a grant in their fiscal year 2002 to immediately apply for funding and it also allows for the States that may not immediately qualify to enact the changes needed in order to qualify and apply for funding in either their fiscal year 2003 or fiscal year 2004. This method is set up to accommodate as many States as possible.

In the May 2, 2003 final rule with comment period, we added § 148.316; paragraph (a) describes the application package that the individual State must submit to document that it has met the requirements for a grant. At a minimum, the package must include a completed standard form application kit (see paragraph (b) of this section) along with the following information:

(1) *History and description of the qualified high risk pool.* Provide a detailed description of the qualified high risk pool that includes the following:

(i) Brief history, including date of inception.

(ii) Enrollment criteria (including provisions for the admission of eligible individuals, as defined in § 148.103) and number of enrollees.

(iii) Description of how coverage is provided administratively in the qualified high risk pool (that is, self-insured, through a private carrier, etc.).

(iv) Benefits options and packages offered in the qualified high risk pool to both HIPAA-eligible individuals (as

defined in § 148.103) and non-HIPAA-eligible individuals.

(v) Outline of plan benefits and coverage offered in the pool and the plan benefits and coverage of the two most popular policies in the State's private individual market.

(vi) Premiums charged (in terms of dollars and in percentage of standard risk rate) and other cost-sharing mechanisms, such as co-pays and deductibles, imposed on enrollees (both eligible individuals (as defined in § 148.103) and non-eligible individuals if a distinction is made).

(vii) How the standard risk rate for the State is calculated and when it was last calculated.

(viii) Revenue sources for the qualified high risk pool, including current funding mechanisms and, if different, future funding mechanisms. Provide current projections of future income.

(ix) Copies of all governing authorities of the pool, including statutes, regulations, and plan of operation.

(2) *Accounting of risk pool losses.* Provide a detailed accounting of claims paid, administrative expenses, and premiums collected for the fiscal year for which the grant is being requested. Indicate the timing of the fiscal year upon which the accounting is based. Provide the methodology of projecting losses and expenses, and include current projections of future operating losses (this information is needed to judge compliance with the requirement in § 148.310(d) of this final rule).

(3) *Contact person.* Identify the name, position title, address, e-mail address, and telephone number of the person to contact for further information and questions.

In paragraph (b)(1) of § 148.316, the following standard forms must be completed with an original signature and enclosed as part of the proposal:

SF-424 Application for Federal Assistance
SF-424A Budget Information
SF-424B Assurances—Non-Construction Program
SF-LLL Disclosure of Lobbying Activities Biographical Sketch
Additional Assurances

These forms can be downloaded from the following Web site: <http://www.cms.hhs.gov/researchers/priorities/grants.asp>.

Paragraph (b)(2) specifies that all other narrative in the application must be submitted on 8½ x 11" white paper.

In paragraph (c), we describe what applicants are required to submit. Applicants are required to submit an original and two copies of the application. Submissions by facsimile (fax) transmission will not be accepted.

Applications mailed through the U.S. Postal Service or a commercial delivery service will be considered "on time" if received by the close of business on the closing date, or postmarked (first class mail) by the date specified in the **DATES** section of this final rule. If express, certified, or registered mail is used, the applicant should obtain a legible dated mailing receipt from the U.S. Postal Service. Private metered postmarks are not acceptable as proof of timely mailings.

In paragraph (d), we describe the deadlines States must meet for submitting an application for losses they incur in a specified fiscal year.

(1) *Deadline for States to submit an application for losses incurred in their fiscal year 2002.* States had to submit an application to us by no later than September 30, 2003.

(2) *Deadline for States to submit an application for losses incurred in their fiscal year 2003.* States must submit an application to us by no later than June 30, 2004.

(3) *Deadline for States to submit an application for losses incurred in their fiscal year 2004.* States must submit an application to us by no later than June 30, 2005.

In paragraph (e), we indicate where to submit an application. All initial applications and supplemental applications must be submitted to: Centers for Medicare & Medicaid Services, Acquisition and Grants Group, Mail Stop C2-21-15, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Nicole Nicholson.

In the May 2, 2003 final rule with comment period, we added § 148.318, which describes how we will review grant applications. Paragraph (a) indicates that this grant program is not listed by the Secretary under 45 CFR 100.3, and therefore the grant program is not subject to review by States under 45 CFR part 100, which implements Executive Order 12372, "Intergovernmental Review of Federal Programs."

Paragraph (b) states that a team consisting of staff from CMS and the Department of Health and Human Services will review all applications. The team will meet as necessary on an ongoing basis as applications are received.

Paragraph (c) describes the eligibility criteria. To be eligible for a grant, a State must submit sufficient documentation to demonstrate that its high risk pool meets the eligibility requirements described in § 148.310. A State must include sufficient documentation of the losses incurred in the operation of the

qualified high risk pool in the period for which it is applying.

Paragraph (d) indicates that if the review team determines that a State meets the eligibility requirements described in § 148.310, the review team will use the following additional criteria in reviewing the applications:

(1) *Documentation of expenses incurred during operation of the qualified high risk pool.* The losses and expenses incurred in the operation of a State's pool are sufficiently documented.

(2) *Funding mechanism.* The State has outlined funding sources, such as assessments and State general revenues, which can cover the projected costs and are reasonably designed to ensure continued funding of losses a State incurs in connection with the operation of the qualified high risk pool after fiscal year 2004.

In the May 2, 2003 final rule with comment period, we added § 148.320, which describes our grant award process. Paragraph (a) provides that we will notify each State applicant in writing of CMS' decision on its application. If we award a grant to the State applicant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see 45 CFR part 92).

(iii) The grantee may be required to submit quarterly progress and financial reports under 45 CFR part 92.

Paragraph (b) specifies that an applicant that receives a grant award must submit a letter of acceptance to CMS' Acquisition and Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

III. Analysis of and Responses to Public Comments

We received five timely public comments in response to the May 2, 2003 final rule with comment period. The comments and our responses are summarized below.

Comment: One commenter was concerned with the requirement in § 148.316(a)(1)(v) that a State applicant provide the plan benefits and coverage of the two most popular policies in the State's private individual market.

The commenter indicated that eligibility for a grant under the Trade Adjustment Assistance Reform Act of

2002 (Trade Act) does not require that the benefits and coverage of the high risk pool relate to the benefits and coverage of the State's most popular plans.

Response: The Trade Act requires that, in order to be eligible for a grant, a State's high risk pool must be a "qualified high risk pool" as defined in section 2744(c)(2) of the Public Health Service Act (PHS Act). A high risk pool, in accordance with section 2744(c)(2), must provide covered benefits consistent with the NAIC Model Health Plan for Uninsurable Individuals Act (NAIC Model) that was in effect at the time of passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Section 8 of the NAIC Model provides two alternatives for a high risk pool to use in designing a benefit package. Alternative One requires that a benefit plan be designed to be "consistent with major medical expense coverage to every eligible person who is not eligible for Medicare." Alternative Two provides a specific menu of benefits and exclusions that can be adopted by the risk pool. In establishing the coverage under alternative two, however, the risk pool board shall promulgate a benefit level "commensurate with health insurance provided through a representative number of large employers in the State." Both of these alternatives clearly indicate that a risk pool should provide a level of coverage that is consistent with what is being provided by other carriers throughout the State. An example of a way to establish that a risk pool is providing coverage that is consistent with what is being provided in the State is to provide both the coverage of the risk pool and that of the two most popular policies in the private individual market. In response to this comment, § 148.316(a)(1)(v) is being amended to specify that a State applicant must demonstrate that its high risk pool is providing coverage consistent with either Alternative One or Alternative Two in section 8 of the NAIC Model. This provides an applicant more flexibility in demonstrating that its risk pool is providing a level of benefits consistent with the NAIC Model.

Comment: One commenter was concerned with our interpretation of "qualified high risk pool" as defined in the Trade Act and section 2744(c)(2) of the PHS Act. The commenter indicated that the intent of the legislation was to provide assistance to all State high risk pools, regardless of whether the pools met the requirements of the PHS Act. The commenter stated that the definition of a "qualified high risk pool"

was inserted in the Trade Act to encourage States to use their high risk pools as their HIPAA mechanism, but not to rule out State high risk pools that did not meet the technical requirements of section 2744(c)(2).

The commenter also expressed concern for the States that have bifurcated pools, one for HIPAA eligibles and one for non-HIPAA eligibles, stating that losses from both pools should be counted for the grant, not just the pool for HIPAA eligibles.

Response: We do not believe there is any ambiguity in the statute. The language of the Trade Act expressly provides that a State must have established a "qualified high risk pool" as defined in section 2744(c)(2) of the PHS Act in order to qualify for a grant. Similarly, with respect to States with bifurcated high risk pools, the risk pools that do not include HIPAA eligibles do not meet the statutory definition of a qualified high risk pool. However, as a practical matter, it is our understanding that the losses from the pools that serve HIPAA eligibles are likely to be high enough to enable those States to obtain their full grant allotment under the allocation formula.

Comment: One commenter requested that the definition of "State" be expanded to include entities that may have been formed by State legislatures to conduct risk pool operations. This would allow the risk pool entity to submit a grant application on behalf of the State. The commenter also requested that "fiscal year" be defined to allow use of either the fiscal year of the State or, if different, the fiscal year of the risk pool entity. This would allow the risk pool entity to submit records based upon its own accounting system, if different from the State's.

Response: We agree with this comment and for purposes of this rule we have added to § 148.308 a definition of "State" that includes a risk pool entity of a State. We also added a definition of "State fiscal year" to include the fiscal year of the risk pool entity of the State.

Comment: One commenter was concerned with the 150 percent of the standard risk rate premium cap requirement. Since each State may calculate its standard risk rate differently, one State's risk pool premium, although set higher than 150 percent of its standard risk rate, may be lower in dollar value than another State's risk pool premium, even though the second State's premium is set lower than 150 percent of its standard risk rate. The commenter also stated that the NAIC Model recommends a premium cap of 200 percent, which, in the

commenter's opinion, was more reasonable.

Response: The statute expressly requires the premium cap to be 150 percent of the standard risk rate. We have no authority to change the premium cap amount.

Comment: One commenter requested that we revise the language in § 148.314 (d) and (e), which explains how we plan to allocate the grant funds, to make it more technically correct in terms of fiscal year appropriations.

Response: We agree with this comment and have revised § 148.314(d) and (e) with the language that was suggested by the commenter.

IV. Provisions of the Final Regulations

For the most part, this final rule adopts the provisions of the May 2, 2003 final rule with comment period. Those provisions of this final rule that differ from the May 2003 final rule with comment period follow.

In response to comments, we revised § 148.308 by adding the definition of "State" to include in the definition an entity that operates the risk pools on behalf of the State. We also added the definition of "State fiscal year" to include fiscal years by which the risk pool entity bases its accounting. We revised § 148.316(a) introductory text to indicate that if a risk pool entity of a State applies for the grant (instead of the State itself), then it must demonstrate the nexus between it and the State. We revised § 148.316(a)(1)(v) to require State applicants to demonstrate that their risk pool is providing benefits coverage that is consistent with either Alternative One or Alternative Two of the NAIC Model.

We also revised § 148.312(b)(1) to indicate that, for grants based upon State fiscal years 2002 and 2003, the 3-year average of the number of uninsured in each State was calculated using CPS statistics available as of September 30, 2003 and for grants based upon State fiscal year 2004, the average number of uninsured will be calculated using CPS statistics available as of September 30, 2004. This change was made to reflect when the Census Bureau releases its annual statistics on the uninsured.

We revised § 148.314(a) to clarify that, when a State becomes eligible for a grant in the middle of its fiscal year, it can apply for a grant based only upon losses its risk pool incurs for the portion of the fiscal year after eligibility is established. We also revised § 148.314(d)(1), (d)(2), (d)(4), and (e) to use technically correct language for Federal fiscal year appropriations.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the section that contains information collection requirements.

Sections 148.316 Grant Application Instructions

This section requires an applicant to submit the application in writing and states what it must contain.

The burden for this information collection requirement has been approved by the Office of Management and Budget under approval number 0938-0887 through July 2006.

This section also requires documentation to be provided by a risk pool entity if it applies on behalf of a State. We estimate that it will take approximately 10 minutes per risk pool entity to provide documentation for a total of 3 hours per year, based on a maximum of 18 risk pool applicants. We will revise the information collection package, 0938-0887, to include this additional burden.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, RDIG, DRD-B, Attn: Dawn Willingham, CMS-2179-F, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Since the amount of appropriations under this rule will not total more than \$40 million per fiscal year, it is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. Since this rule is implementing a grant program for the States, this rule will not have a significant impact on small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. Again, since this rule is implementing a grant program for the States, it will not have a significant impact on small hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the

private sector, of \$110 million. Since this rule is strictly an appropriation, there are no unfunded mandates included in the rule.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this rule is strictly an appropriation of \$80 million to the States to fund losses incurred in the operation of qualified high risk pools, it will have a beneficial impact on State governments since the funds will be used to provide health insurance coverage to uninsured individuals and will not impose any direct requirement costs on State and local governments.

B. Anticipated Effects

This rule will have a positive impact on approximately 22 States that currently operate qualified high risk pools in that it will make funds available to those States to fund losses incurred in the operation of their high risk pools. Additionally, in order to be eligible for funding, the high risk pools will have to lower or maintain their premium cap at no higher than 150 percent of the standard rate in the private market. These grants, therefore, will serve as an incentive for States to keep their risk pool premiums at a level that will be affordable and accessible to more uninsured individuals. It will not have a significant impact on other entities, including providers, nor will it have any significant impact on the Medicare and Medicaid programs.

C. Alternatives Considered

The Trade Adjustment Assistance Reform Act of 2002 was very prescriptive in its criteria for eligibility for operation grants to high risk pools. It also provided a specific definition of a high risk pool and outlined the allocation formula for the grants. In addition to following the statute, we had to comply with the Department grant award procedure requirements. Because of these requirements, and because we wanted to make the money available as quickly as possible, we did not consider other major alternatives on how to award the grants.

D. Conclusion

For the reasons indicated elsewhere in this section, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a

substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects in 45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subchapter B part 148 as set forth below:

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

■ 1. The authority citation for part 148 continues to read as follows:

Authority: Secs 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg-41 through 300gg-63, 300gg-91, and 300gg-92).

■ 2. In § 148.308, add the definitions of “State” and “State fiscal year” in alphabetical order to read as follows:

§ 148.308 Definitions.

* * * * *

State, for purposes of this subpart, means any of the 50 States and the District of Columbia or any entity to which a State has delegated the authority to conduct risk pool operations.

State fiscal year, for purposes of this subpart, means the fiscal year used for accounting purposes by either a State or a risk pool entity to which a State has delegated the authority to conduct risk pool operations.

■ 3. In § 148.312, republish the introductory text of paragraph (b) and revise paragraph (b)(1) to read as follows:

§ 148.312 Amount of grant payment.

* * * * *

(b) Funds will be allocated to each eligible State in accordance with the following formula:

(1) The number of uninsured individuals is calculated for each eligible State by taking a 3-year average of the number of uninsured individuals in that State in the Current Population Survey (CPS) of the Census Bureau. For grants based upon State fiscal years 2002 and 2003, a 3-year average was calculated using numbers available as of September 30, 2003. For grants based upon State fiscal year 2004, a 3-year average will be calculated using

numbers available as of September 30, 2004.

* * * * *

■ 4. Amend § 148.314 as follows:

- A. Revise paragraph (a).
- B. Revise paragraph (d)(1).
- C. Revise paragraph (d)(2).
- D. Revise paragraph (d)(4).
- E. Revise paragraph (e).

The revisions read as follows:

§ 148.314 Periods during which eligible States may apply for a grant.

(a) *General rule.* A State that meets the eligibility requirements in § 148.310 may apply for a grant to fund losses that were incurred during the State's fiscal year 2002, 2003, or 2004 in connection with the operation of its qualified high risk pool. If a State becomes eligible for a grant in the middle of its fiscal year, a State may apply for losses incurred in a partial fiscal year if a partial year audit is done. Only losses that are incurred after eligibility is established will qualify for a grant.

* * * * *

(d) * * *

(1) *Initial grant applications submitted for losses incurred in State fiscal year 2002 (hereafter referred to as 02 States).* Initial grants to States that submitted an application for losses incurred in State fiscal year 2002 were funded out of the \$40 million appropriation for Federal fiscal year (FFY) 2003, which is available for obligation until the end of FFY 2004. (This is referred to as the "initial \$40 million appropriation.")

(2) *Initial grant applications submitted for losses incurred in State fiscal year 2003 (hereafter referred to as 03 States).* Initial grants to States that did not submit an application for losses in State fiscal year 2002 (or submitted an application but did not qualify) and first qualified for a grant for losses incurred in State fiscal year 2003 will be funded out of the initial \$40 million appropriation.

* * * * *

(4) *Other applications.* All other grants, including the initial grants for the 04 States (States that initially qualify based upon losses incurred in their fiscal year 2004), will be funded out of the \$40 million appropriation for FFY 2004, which is available for obligation until the end of FFY 2005. (This is referred to as the "second \$40 million appropriation.")

(e) *Allocation of funds.* Grants to States described in paragraphs (d)(1) and (d)(2) of this section will be allocated in accordance with paragraphs (e)(1) and (e)(2) of this section.

(1) *Initial allocation.* (i) *Reserves.* We will first determine the projected

number of 03 States (those that are expected to submit their initial grant requests after the deadline for grants relating to a State's 2002 losses). We will reserve the portion of the initial \$40 million appropriation that we estimate will be needed to fund grants for 03 States.

(ii) *Initial allocation to 02 States.* The remainder of the initial \$40 million appropriation will be allotted to the 02 States.

(iii) *Excess reserves.* If the initial allotments for any of the 02 or 03 States are less than 50 percent of the losses incurred by those States, any reserved funds that remain after allotments have been made to all 02 and 03 States will be proportionally redistributed to the 02 and 03 States, but not to exceed 50 percent of losses incurred by the States. The size of the initial grants will be increased retroactively for those States.

(2) *Second allocation.* The procedure described in paragraph (e)(1) of this section will also be applied to allocate the second \$40 million appropriation. A reserve will be established based on the amounts expected to be needed to fund grants to 04 States before funds are allocated for second year grants for 02 and 03 States. If any excess funds remain after States receive their full allotments, the funds will be proportionally distributed to States whose allotments were less than 50 percent of their losses.

■ 5. Amend § 148.316 as follows:

- A. Revise paragraph (a) introductory text.
- B. Republish the introductory text of paragraph (a)(1).
- C. Revise paragraph (a)(1)(v).

The revisions read as follows:

§ 148.316 Grant application instructions.

(a) *Application package.* Each State must compile an application package that documents that it has met the requirements for a grant. If a risk pool entity applies on behalf of a State, it must provide documentation that it has been delegated appropriate authority by the State. At a minimum, the application package must include a completed standard form application kit (see paragraph (b) of this section) along with the following information:

(1) *History and description of the qualified high risk pool.* Provide a detailed description of the qualified high risk pool that includes the following:

* * * * *

(v) Outline of plan benefits and coverage offered in the pool. Provide evidence that the level of plan benefits is consistent with either Alternative One

or Alternative Two in Section 8 of the NAIC Model Health Plan for Uninsurable Individuals Act. See Appendix for the text of Section 8 of the NAIC Model.

* * * * *

(Catalogue of Federal Domestic Assistance Program No. 93.780, Grants to States for Operation of Qualified High-Risk Pools)

Dated: October 30, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 22, 2003.

Tommy G. Thompson,

Secretary.

Note: This appendix will not appear in the Code of Federal Regulations.

Appendix

NAIC Model Health Plan for Uninsurable Individuals Act—July 1997 (This version is identical to the version that was in effect as of August 21, 1996)

Section 8. Benefits

Drafting Note: Two alternatives for Subsection A are offered for establishing covered services for the plan. Alternative One provides for the plan board to establish the covered services and exclusions, subject to the approval of the Commissioner. The advantages of this alternative are that legislators can leave the benefit determinations to experts in plan design and that benefits can be easily modified from time to time to recognize changes in marketplace standards and medical technology.

Alternative Two contains a list of covered services and exclusions for states that wish to include the benefits and exclusions in the statute. The advantage of Alternative Two is that the list contains the benefits and exclusions found in some high risk plans in operation at the time the model was adopted. The list is intended to be inclusive and states may wish to add or delete benefits or exclusions to reflect the state's policy preferences. The list is an outline of the benefits and exclusions; it is not policy language.

Consideration should be given prior to enactment to the cost effectiveness of inclusion or deletion of benefit mandates or other minimum benefit standards. Consideration also should be given to providing sufficient flexibility in the plan to allow for the delivery of services through health maintenance organizations, preferred provider organizations and other managed care arrangements.

Alternative One

A. The plan shall offer health care coverage consistent with major medical expense coverage to every eligible person who is not eligible for Medicare. The coverage to be issued by the plan, its schedule of benefits, exclusions and other limitations shall be established by the board and subject to the approval of the Commissioner.

Alternative Two

A. (1) Outline of Benefits. Covered expenses shall be the usual, customary and reasonable charge in the locality for the following services and articles when prescribed by a physician and determined by the plan to be medically necessary for the following areas of services, subject to provisions of Subsection B:

- (a) Hospital services;
 - (b) Professional services for the diagnosis or treatment of injuries, illnesses or conditions, other than mental or dental, which are rendered by a physician, or by other licensed professionals at his direction;
 - (c) Drugs requiring a physician's prescription;
 - (d) Skilled nursing services of a licensed skilled nursing facility for not more than 120 days during a policy year;
 - (e) Services of a home health agency up to a maximum of 270 services per year;
 - (f) Use of radium or other radioactive materials;
 - (g) Oxygen;
 - (h) Anesthetics;
 - (i) Prostheses other than dental;
 - (j) Rental of durable medical equipment, other than eyeglasses and hearing aids, for which there is no personal use in the absence of the conditions for which it is prescribed;
 - (k) Diagnostic X-rays and laboratory tests;
 - (1) Oral surgery for excision of partially or completely unerupted, impacted teeth or the gums and tissues of the mouth when not performed in connection with the extraction or repair of teeth;
 - (m) Services of a physical therapist;
 - (n) Emergency and other medically necessary transportation provided by a licensed ambulance service to the nearest facility qualified to treat a covered condition;
 - (o) Outpatient services for diagnosis and treatment of mental and nervous disorders provided that a covered person shall be required to make a fifty percent (50%) copayment, and that the plan's payment shall not exceed \$[insert number].
- (2) Exclusions. Covered expenses shall not include the following:
- (a) Any charge for treatment for cosmetic purposes other than surgery for the repair or treatment of an injury or a congenital bodily defect to restore normal bodily functions;
 - (b) Care which is primarily for custodial or domiciliary purposes;
 - (c) Any charge for confinement in a private room to the extent it is in excess of the institution's charge for its most common semiprivate room, unless a private room is medically necessary;
 - (d) That part of any charge for services rendered or articles prescribed by a physician, dentist or other health care personnel which exceeds the prevailing charge in the locality or for any charge not medically necessary;
 - (e) Any charge for services or articles the provision of which is not within the scope of authorized practice of the institution or individual providing the services or articles;
 - (f) Any expense incurred prior to the effective date of coverage by the plan for the person on whose behalf the expense is incurred;
 - (g) Dental care except as provided in Subsection A(1)(1);

- (h) Eyeglasses and hearing aids;
 - (i) Illness or injury due to acts of war;
 - (j) Services of blood donors and any fee for failure to replace the first three (3) pints of blood provided to an eligible person each policy year;
 - (k) Personal supplies or services provided by a hospital or nursing home, or any other nonmedical or nonprescribed supply or service;
 - (1) Routine maternity charges for a pregnancy, except where added as optional coverage with payment of additional premiums;
 - (m) Any expense or charge for services, drugs or supplies that are not provided in accord with generally accepted standards of current medical practice;
 - (n) Any expense or charge for routine physical examinations or tests;
 - (o) Any expense for which a charge is not made in the absence of insurance or for which there is no legal obligation on the part of the patient to pay;
 - (p) Any expense incurred for benefits provided under the laws of the United States and this state, including Medicare and Medicaid and other medical assistance, military service-connected disability payments, medical services provided for members of the armed forces and their dependents or employees of the armed forces of the United States, and medical services financed on behalf of all citizens by the United States;
 - (q) Any expense or charge for in vitro fertilization, artificial insemination, or any other artificial means used to cause pregnancy;
 - (r) Any expense or charge for oral contraceptives used for birth control or any other temporary birth control measures;
 - (s) Any expense or charge for sterilization or sterilization reversals;
 - (t) Any expense or charge for weight loss programs, exercise equipment or treatment of obesity, except when certified by a physician as morbid obesity (at least two (2) times normal body weight);
 - (u) Any expense or charge for acupuncture treatment unless used as an anesthetic agent for a covered surgery;
 - (v) Any expense or charge for organ or bone marrow transplants other than those performed at a hospital with a board approved organ transplant program that has been designated by the board as a preferred provider organization for that specific organ or bone marrow transplant;
 - (w) Any expense or charge for procedures, treatments, equipment, or, services that are provided in special settings for research purposes or in a controlled environment, are being studied for safety, efficiency, and effectiveness, and are awaiting endorsement by the appropriate national medical specialty college for general use within the medical community.
- B. In establishing the plan coverage, the board shall take into consideration the levels of health insurance provided in the state and medical economic factors as may be deemed appropriate; and promulgate benefit levels, deductibles, coinsurance factors, exclusions and limitations determined to be generally reflective of and commensurate with health

insurance provided through a representative number of large employers in the state.

C. The board may adjust any deductibles and coinsurance factors annually according to the Medical Component of the Consumer Price Index.

D. Preexisting Conditions.

(1) Plan coverage shall exclude charges or expenses incurred during the first six (6) months following the effective date of coverage as to any condition for which medical advice, care or treatment was recommended or received as to such conditions during the six-month period immediately preceding the effective date of coverage.

Drafting Note: In order to reduce the premiums and costs of the plan, states may wish to provide for a longer exclusion period for preexisting conditions. States will need to weigh the need to provide access to individuals with preexisting conditions with the increased costs associated with a shorter preexisting condition exclusion period.

(2) Such preexisting condition exclusions shall be waived to the extent that similar exclusions, if any, have been satisfied under any prior health insurance coverage which was involuntarily terminated; provided, that

(1) Application for pool coverage is made not later than sixty (60) days following such involuntary termination and, in such case, coverage in the plan shall be effective from the date on which such prior coverage was terminated; and

(b) The applicant is not eligible for continuation or conversion rights that would provide coverage substantially similar to plan coverage.

E. Nonduplication of Benefits.

(1) The plan shall be payer for last resort of benefits whenever any other benefit or source of third-party payment is available. Benefits otherwise payable under plan coverage shall be reduced by all amounts paid or payable through any other health insurance and by all hospital and medical expense benefits paid or payable under any workers' compensation coverage, automobile medical payment or liability insurance whether provided on the basis of fault or nonfault, and by any hospital or medical benefits paid or payable under or provided pursuant to any state or federal law or program.

(2) The plan shall have a cause of action against an eligible person for the recovery of the amount of benefits paid that are not for covered expenses. Benefits due from the plan may be reduced or refused as a set-off against any amount recoverable under this paragraph.

[FR Doc. 04-6852 Filed 3-25-04; 8:45 am]

BILLING CODE 4120-01-P