order to avoid reversion of the RCRA program to EPA.

B. End of Interim Authorization Application Period

Section 123.122(c)(1) provides that a State may apply for interim authorization until the end of the 6th month after the effective date of the last Phase II component. The interim authorization application period will close on July 26, 1983.

EPA is amending this provision elsewhere in today's **Federal Register** by adding that "the Regional Administrator may extend the application period for good cause." The preamble to this amendment notes that "EPA intends that this extension only be granted on a case-by-case basis to States which have made a good faith effort to meet the application deadline and which can submit a complete application within a reasonable period of time".

C. States With Partial Interim Authorization

Section 123.122(c)(4), as amended elsewhere in today's **Federal Register**, requires States which have received partial interim authorization (i.e., interim authorization for Phase I alone or Phase I and some components of Phase II) to apply for *all* of Phase II within 6 months of the effective date of the last component of Phase II. This deadline will occur on July 26, 1983. Section 123.137 contains the related stipulation that State programs with partial interim authorization which fail to submit an amended application for all of Phase II which meets the requirements of the Federal program by the above deadline will terminate and responsibility for RCRA implementation will revert to EPA.

Alternatively, State programs with partial interim authorization can avoid program reversion to EPA by applying for and receiving final authorization by the above deadline. In addition, today's amendments to these two sections provide that the Regional Administrator may extend the deadline for good cause. This extension is intended to be granted in the same amanner as the extension to the application deadline discussed earlier.

D. Deadline for State Enabling Legislation

RCRA Section 3006(c) provides that interim authorization may be granted to those States which have "in existence a hazardous waste program pursuant to State law" no more than 90 days after the "promulgation of regulations under Sections 3002, 3003, 3004, and 3005." EPA interprets this provision to mean that, at a minimum, a State must have basic enabling legislation for the program in place, i.e., basic statutory authority to regulate hazardous waste, in order to be eligible for interim authorization.

The deadline by which the State enabling legislation must be in place is found in § 123.125(a). This section is amended elsewhere in today's **Federal Register** to tie the deadline to the final Phase II component, which establishes the last major elements of the Federal program. This section is revised to provide that: "The State Attorney General or independent legal counsel must certify that the enabling legislation for the State's program was in existence within 90 days of the announcement of the last component of Phase II." This deadline will occur on October 25, 1982.

Most States which have received interim authorization for Phase I will have already demonstrated adequate authority and thus satisfied the enabling legislation requirement. Unauthorized States which desire to apply for interim authorization can satisfy the requirement by certifying that the necessary legislation was in place at any time prior to the date given above.

V. Compliance With Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. The notice published today is not major because it will not result in an effect on the economy of $100 million or more and will not result in an increase in costs or prices. It will not result in any of the other significant adverse effects addressed in the Executive Order. The notice announces the last component of Phase II interim authorization, the beginning of final authorization, and several deadlines in the interim authorization process. These announcements are based on and carry out regulations promulgated under RCRA.

This notice was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

VI. Authority

Sections 1006, 2002(a) and 3006 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. 6905, 6912(a) and 6926.

List of Subjects in 40 CFR Part 123

Hazardous materials, Indians-lands, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control, Water supply, Intergovernmental relations, Penalties, Confidential business information.

Dated: July 9, 1982.

Anne M. Gorsuch,

Administrator.

[FR Doc. 82-19471 Filed 7-23-82; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 264

[SW-FRL 2173-1]

Hazardous Waste Management System; Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule.

SUMMARY: Elsewhere in today's **Federal Register**, EPA announces that States may commence the application process for final authorization. As described in that announcement, EPA plans to add permitting standards for several processes which are not currently covered by the Part 264 standards for owners and operators of hazardous waste management facilities. Section 123.13(e) requires States with final authorization to make revisions to their programs "within one year of the date of promulgation of such [Federal] regulations, unless a State must amend or enact a statute . . . in which case such revision shall take place within two years." Under the current regulations, until a State makes those revisions, neither EPA nor that State has the authority to issue RCRA permits to facilities covered by those new permitting standards, including new facilities which need a RCRA permit in order to commence operation (and, in some cases, construction).

To remedy this problem, EPA is today amending its hazardous waste management regulations to enable certain facilities located in States with final authorization to obtain a federally-issued RCRA permit during the time preceding the State's authorization for those new standards. EPA is also today clarifying the applicability of new permit standards in States with Phase II interim authorization.

The Agency expects that this amendment will result in savings to the regulated community by enabling new facilities subject to these post-authorization standards to obtain a RCRA permit and begin operation before the State adopts equivalent new

standards. New facilities are expected to operate with a higher level of environmental protection than older, more conventional facilities. Therefore, this amendment will have a positive environmental impact by allowing these new facilities to obtain RCRA permits sooner than they would otherwise be able.

DATES: *Effective date:* January 26, 1983.

Comment date: EPA will accept public comment on this amendment until September 24, 1982.

ADDRESS: Comments should be sent to the Docket Clerk (Docket 3004—Additions to federal regulations after state authorization), Office of Solid Waste (WH–562), Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Terrance Grogan, Office of Solid Waste (WH–563), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, (202) 382–2224; or the RCRA Hotline toll-free at (800) 424–9346 or in Washington, D.C. at 382–3000.

SUPPLEMENTARY INFORMATION:

I. Background

On February 26, 1980, and May 19, 1980, EPA published regulations pursuant to the Resource Conservation and Recovery Act of 1976, as amended (RCRA), establishing the first phase of a comprehensive program for the handling and management of hazardous waste (45 FR 33066–33285, now codified in 40 CFR Parts 260–265). These regulations require, among other things, that facilities which treat, store, or dispose of hazardous waste must obtain a permit from EPA or an authorized State. The permit must be based on standards promulgated by EPA in 40 CFR Part 264.[1]

Section 3006 of RCRA allows a State which seeks to administer and enforce a hazardous waste program to obtain authorization from EPA to run the program in lieu of the Federal Government. EPA will authorize a State if it determines that the State's program is "equivalent" to and "consistent" with (in the case of final authorization), or "substantially equivalent" to (in the case of interim authorization), the Federal program. The authorized State can then issue and enforce permits for the treatment, storage, or disposal of hazardous waste, under RCRA.[2]

On May 19, 1980, EPA promulgated regulations which spell out in detail, among other things, the requirements for States to receive authorization to administer the RCRA permit program in lieu of the Federal permit program. (See 45 FR 33377, codified in 40 CFR Part 123).

Elsewhere in today's **Federal Register**, EPA is promulgating permitting standards for land disposal facilities, which represent the last major piece of the RCRA hazardous waste program. However, EPA intends to add permitting standards for processes not currently covered by the Part 264 standards. For example, the Part 264 standards do not currently cover treatment and storage of hazardous waste in certain types of underground tanks; thermal treatment of hazardous waste in devices other than incinerators; or treatment of hazardous waste by chemical, physical or biological methods (other than in tanks, surface impoundments or land treatment units).

Adding Part 264 permitting standards to the Federal regulations after States have obtained final authorization raises the following problem under the existing regulations. Section 123.13(e) provides that State programs approved for final authorization must make revisions required by changes to the Federal RCRA program "within one year of the date of promulgation of such [new or modified] regulation, unless a State must amend or enact a statute in order to make the required revision in which case such revisions shall take place within two years." This language provides a clear and orderly process for maintaining the "equivalence" of State programs that have received final authorization. However, there may still be a one or two year gap between the time new standards are promulgated by EPA, and the time that the State adopts and is authorized for equivalent standards.

The problem arises when a person plans to build a new facility (or expand an existing one) with processes covered by the new Part 264 standards during this one or two year period in a State with final authorization.[3] Such a person could not receive a RCRA permit for these processes from the authorized State during this period. This is because the State's RCRA authorization includes only those portions of the Federal program for which the State has been judged to have equivalent and consistent standards. State programs cannot operate "in lieu of" this new part of the Federal program until they have received authorization for those new Part 264 standards.

In addition, the person could not receive a federally-issued RCRA permit if he or she is located in a State with final authorization, because § 264.1(f) as currently worded provides that the requirements of Part 264 do not apply to a person who treats, stores or disposes of hazardous waste in a State with a RCRA hazardous waste program authorized under Part 123.[4] (This provision was originally promulgated on the assumption that by the time of final authorization, Part 264 standards would be in place for all categories of facilities.)

The owner or operator of a new facility could therefore face a period of time in which he cannot obtain a RCRA permit from either the authorized State or the Federal government. This effectively places a ban on the operation (and, in some cases, construction) of the facility. EPA did not intend to impose this de facto ban, and believes it is undesirable. These new facilities may provide needed additional treatment, storage, and disposal capacity at a higher level of environmental protection than older, more conventional facilities.

The Agency is today amending § 264.1(f) to rectify this problem. Under this amendment, Part 264 will apply to these facilities until the State receives final authorization for the new standards. Facilities subject to these new standards may therefore obtain a federally-issued RCRA permit during that limited period of time. They will not have to wait until the State in which they are located adopts equivalent and consistent standards.

The language of § 264.1(f) is also being amended to clarify the applicability of Part 264 in States with Phase II interim authorization under RCRA § 3006(c).[5] This amendment ensures that States authorized for any of the Phase II components will operate the RCRA permit program in lieu of EPA for facilities covered in their authorized components. For example, if a facility conducted incineration of hazardous wastes, and the facility was located in a State with interim authorization for Phase II, Component B (the component covering incinerators), then it would not

[1] Portions of 40 CFR Part 264 were promulgated on May 19, 1980 (45 *FR* 33154), January 12, 1981 (46 *FR* 2802), and January 23, 1981 (45 *FR* 7667). The major missing piece of the RCRA performance standards was the land disposal regulations, until their promulgation elsewhere in today's **Federal Register**.

[2] States may issue hazardous waste permits under State law in any case, whether or not they are authorized under RCRA.

[3] Facilities in existence on November 19, 1980, may qualify for interim status when the new standards are promulgated. See Section 3005(e) of RCRA and 40 CFR Part 122.22(a).

[4] Part 264 does currently apply to underground injection, if the authorized State program does not cover it. See 40 CFR § 264.1(f).

[5] For a discussion of Phase II interim authorization, see amendments to Part 123 published on January 26, 1981, 46 FR 8298, and the announcement of Phase II Component C elsewhere in today's **Federal Register**.

be subject to Part 264, and the State's "substantially equivalent" standards would operate in lieu of the Federal standards.

However, Part 264 will apply to the permitting of new processes (e.g., underground tanks) added to the coverage of Part 264 after the announcement of Component C. Since Component C is the last Phase II component, interim authorization would not be available for permitting these new processes. EPA would retain permitting responsibility for such new processes in States with interim authorization, since the processes would not be included in the State's authorization for Phase II. States would receive authorization to operate the RCRA permit program in lieu of EPA for such new processes as part of final authorization, under the provisions in § 123.13(e) described above.

EPA requests comments on the approach taken in this amendment for both final and interim authorization. In particular, comments are solicited on alternatives to Federal permit issuance in authorized States during the period between addition of new RCRA permit standards and State authorization for equivalent and consistent standards.

II. Interim Final Promulgation

EPA believes that the use of advance notice and comment procedures for this amendment to the applicability section of 40 CFR Part 264 would be impracticable and contrary to the public interest, and therefore finds that good cause exists for adopting this change in interim final form (see 5 U.S.C. § 553(b)(B)).

This amendment is designed to make the language of § 264.1(f) consistent with the Agency's original intent in promulgating that section. EPA never intended a situation where a facility could not obtain a RCRA permit from either EPA or an authorized State after the appropriate Part 264 standards were promulgated. The current language of § 264.1(f) was based on the assumption that Part 264 standards would be in place for all categories of facilities by the time of final authorization. However, this did not happen, and thus certain new facilities could face a temporary ban on operation (and, in some cases, construction) in States with final authorization due to current regulatory language. Today's amendment rectifies this situation by allowing continued operation of the RCRA permitting process, as originally intended.

This interim final amendment will take effect in six months, at the same time that final authorization can take effect. This timing ensures that the RCRA permitting process will not be disrupted in States with final authorization.

EPA will accept comments on this amendment for 60 days, and will make any further changes deemed necessary as a result of those comments.

III. Executive Order 12291

Under Executive Order 12291, (46 FR 12193, February 19, 1981), EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. A major rule is defined as a regulation which is likely to result in:

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This regulation is not major because it will not result in an effect on the economy of $100 million or more nor will it result in a major increase in costs or prices to consumers, industry or government entities. There will be no adverse impact on the ability of the U.S. based enterprises to compete with foreign based enterprises in domestic or export markets. Because this amendment is not a major regulation, no Regulatory Impact Analysis is being prepared.

This amendment was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

IV. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. § 601 *et seq.*, whenever an agency is required to publish a rulemaking, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). No regulatory flexibility analysis is required, however, if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This amendment will not have a significant economic impact on a substantial number of small entities. Accordingly, I hereby certify that this regulation, if issued in final form, will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 264

Hazardous materials, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Waste treatment and disposal.

Dated: July 9, 1982.

Anne M. Gorsuch,

Administrator.

Title 40 CFR Part 264 is amended as follows:

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for Part 264 reads as follows:

Authority: Secs. 1006, 2002(a), and 3004, Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, (42 U.S.C. §§ 6905, 6912(a), and 6924).

2. Section 264.1(f) is revised to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(f) The requirements of this part do not apply to a person who treats, stores, or disposes of hazardous waste in a State with a RCRA hazardous waste program authorized under Subparts A and B of Part 123 of this chapter, or in a State authorized under Subpart F of Part 123 of this chapter for the component or components of Phase II interim authorization which correspond to the person's treatment, storage or disposal processes; except that this part will apply:

(1) As stated in paragraph (d) of this section, if the authorized State RCRA program does not cover disposal of hazardous waste by means of underground injection; and

(2) To a person who treats, stores or disposes of hazardous waste in a State authorized under Subparts A and B of Part 123 of this chapter, at a facility which was not covered by standards under this part when the State obtained authorization, and for which EPA promulgates standards under this part after the State is authorized. This paragraph will only apply until the State is authorized to permit such facilities under Subparts A and B of Part 123 of this chapter.

* * * * *

[FR Doc. 82-19470 Filed 7-23-82; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 265

[SWH-FRL 2173-3]

Hazardous Waste Management System: Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

AGENCY: Environmental Protection Agency.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: Elsewhere in today's Federal Register the Environmental Protection Agency is promulgating standards around which hazardous waste surface impoundments, waste piles, land treatment units, and landfills will be permitted. These rules suggest some conforming changes to Part 265, the Interim Status Standards, for consistency and compatibility. Most of these are promulgated as part of today's rulemaking. A few however, potentially have more impact and could benefit, in the Agency's view, from additional public input. For these reasons,the Agency is proposing the following conforming changes.

(1) A variance to the two foot freeboard requirement for surface impoundments.

(2) Final cover performance requirements for surface impoundments and landfills.

(3) An additional variance allowing placement of some ignitable or reactive wastes in surface impoundments.

(4) More definitive requirements respecting placement of containers in landfills.

DATES: EPA will accept comments on the proposed rules on or before November 23, 1982.

ADDRESS: Comments should be sent to Docket Clerk (Docket 3004—Land Disposal Interim Status Proposal), Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

The public docket for this proposed rule is located in Room S-269, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C., and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline at 800-424-9346 (in Washington, D.C. call 382-3000) or Rodney Jenkins (202) 382-4658, Office of Solid Waste (WH-564), U.S. Environmental Protection Agency, Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION:

I. Explanation of the Proposal

Elsewhere in today's Federal Register, EPA has promulgated regulations affecting treatment, storage, and disposal of hazardous wastes in surface impoundments, waste piles, land treatment units, and landfills. Those rules establish standards that must be met for facilities to receive a permit under the Resource Conservation and Recovery Act (RCRA) hazardous waste regulatory program. Also included are a series of conforming changes to the interim status requirements of Part 265, which were made to provide consistency and compatibility. There are, however, a few additional conforming changes which the Agency believes should be adopted during interim status. Because they may have substantial impact on interim status operations as well as on the environment, and because, in most cases, the public has not had sufficient opportunity to comment on the appropriateness of applying them to the interim status period, EPA is proposing these changes today.

A. Surface Impoundments—General Operating Requirements

Section 265.222 contains the rules designed to prevent overtopping of impoundment dikes. The current interim status regulations require not only that overtopping not occur but that a minimum freeboard of two feet be maintained to ensure it. The Agency received numerous comments claiming that the two foot requirement is not necessary if the performance requirement to prevent overtopping is in place. In any event, some claimed, the two foot minimum might not be suffcient in some cases.

EPA generally agrees with these commenters and, in the Part 264 regulations, the Agency requires only that overtopping be prevented. As with most Part 264 requirements, this will be implemented through the permitting process, when the applicant will demonstrate that design features and operating practices at the facility will, in fact, prevent overtopping. During interim status, in the absence of Agency review provided by the permitting process, EPA has concern that a general performance requirement, such as "prevent overtopping", can be adequately self-implementing or readily enforced. Therefore, the Agency is proposing today to expand the two feet minimum freeboard requirement by allowing a lesser level if a qualified engineer certifies that alternate design features or operating procedures will prevent overtopping. EPA believes that a qualified engineer can review design and operating features and adequately conclude whether overtopping is possible. The owner or operator would also be required to maintain the certification and the basis for it at the facility to facilitate enforcement inspections. The Agency believes this approach to be self-implementable and to provide a degree of protection equivalent to that of the two foot minimum.

B. Surface Impoundments—Closure and Post-Closure Care

The current interim status requirements allow surface impoundments to be closed by digging up remaining wastes and contaminated liners, equipment, and surrounding soils. Alternately, the owner or operator may solidify liquids and apply a final cover in accordance with the landfill requirements for closure (§ 265.310). Also, in the second case, he must carry out the post-closure care requirements as if his impoundment were a landfill.

The Agency does not propose to change this basic approach and, in fact, has adopted it as the basis for the Part 264 permitting standards. EPA believes that the new standards in Part 264 are more easily understood and that they are as applicable during interim status as for permitted facilities. The Agency further believes the new Part 264 rules are readily implementable during interim status as well since the existing interim status closure and post-closure care review process is similar to the review process for closure and post-closure care plans conducted during the permitting process. Therefore, the Agency is proposing to adopt, as interim status requirements, the new Part 264 closure and post-closure care requirements for surface impoundments (§ 264.228) except for some of the post-closure care requirements. (Interim status facilities are not required to have leak detection systems or leachate management facilities and, thus, the post-closure requirements of Part 264 respecting them are inappropriate for interim status facilities.)

The fundamental requirements are not greatly different than the interim status requirements promulgated on May 19, 1980. The new requirements proposed today are, however, much more explicit, identifying more clearly what is expected of the final cover. They are also somewhat more stringent. The cover must now "minimize" infiltration instead of simply "controlling" it. It must not be any more permeable than the bottom liner to prevent the "bathtub"

effect. Since the bottom liner may be highly impermeable, the cap may also have to be impermeable as well. It must also accommodate settling and subsidence. The reasons for these requirements are discussed at length in the preamble to the Part 264 requirements promulgated today elsewhere in this issue of the **Federal Register.**

The proposed interim status post-closure care requirements also contain some differences from those now in place. The new provisions require that erosion from precipitation be prevented. This requirement is appropriate for interim status just as it is for permitted units. The current interim status provisions relating to leachate collection systems, gas collection systems, maintenance of benchmarks, and restriction of access would be dropped as inappropriate under this Proposal, the first three because surface impoundments are not required to have such equipment, and the last because it is redundant to § 265.117(b).

C. Surface Impoundments—Ignitable or Reactive Waste

The existing limitations on placing ignitable or reactive waste in surface impoundments allow the practice only if placing the waste in the impoundment results in the waste not being ignitable or reactive any more; or the impoundment is used solely for emergencies. The new Part 264 requirements allow use of impoundments for ignitable or reactive waste if the waste is protected from conditions that could cause it to ignite or react. EPA doesn't expect this variance to be used much, but concedes that protection against carelessly thrown matches and from certain reactions may be practical. Since the management methods providing protection can be reviewed during permitting, EPA agrees that the new variance provides additional flexibility to the owner or operator without sacrificing human health or environmental protection.

Adoption of the same variance during interim status, however, is fraught with the same enforcement and self-implementation problems as adoption of the freeboard variance discussed in Section A. The Agency proposes to circumvent these difficulties by using the same approach proposed for the freeboard variance, namely that the owner or operator obtain certification from a qualified chemist or engineer that the design features of this facility or the operating practices employed will prevent ignition or reaction. EPA expects that a qualified engineer or chemist can evaluate the operation and adequately determine that it is safe. Enforcement of the rule can adequately be carried out by comparing the basis for the certification kept at the facility against actual practice.

D. Landfills—Closure and Post-Closure Care

The Part 264 Subpart N requirements for closure and post-closure care promulgated today elsewhere in this **Federal Register,** are being proposed here in modified form for adoption as interim status rules. As discussed in Section B of this preamble for surface impoundments, the new rules are clearer and more explicit. Because of this, they should be more easily implemented during interim status than the existing rules.

The interim status closure and post-closure requirements in place now are very general in nature, requiring that owners or operators develop a plan to "control" infiltration based on consideration of certain factors. The new requirements are more specific and are more stringent. Covers must be designed to "minimize" infiltration instead of simply "controlling" it. They must also allow no more precipitation to pass through than would the bottom liner to prevent the "bathtub effect". Additionally, the cover must accommodate settling and subsidence. These provisions are as applicable to landfills which close under interim status as they are to permitted landfills.

The post-closure care requirements for interim status units adopted today are somewhat different than those adopted in Part 264. The Part 264 provisions include some requirements relating to unit components (e.g., leachate collection and treatment systems) which are not required during interim status. Post-closure care provisions affecting these systems would, therefore, be inappropriate.

E. Landfills—Special Requirements for Containers

The current interim status requirements mandate that empty containers be crushed flat prior to placement in the landfill. The purpose of this requirement is to minimize subsidence due to empty containers. Collapse of empty containers is thought to be a leading cause of differential subsidence which in turn poses a serious threat to the continuity and proper functioning of the final cover.

Commenters on this provision made three basic points:

(1) Small containers should be exempted,

(2) Provide guidance on when a container is empty (or full) for purposes of this rule, and

(3) Provide guidance on how much crushing and shredding is necessary to comply.

The agency agrees with all of these points, and, in the Part 264 requirements promulgated today, has accommodated points (1) and (2). The rationale for the various provisions is discussed in the Preamble to that issuance. EPA believes those provisions respond to the commenters requests with regard to interim status but wishes to propose them to obtain added comment.

The Agency is not yet able to provide more specific general guidance at present on how much shredding or crushing is necessary to comply with the rule. EPA believes that crushing sufficiently to produce a void space of 10 percent or less of the volume originally present should adequately minimize differential subsidence. The Agency is not absolutely certain, however, that shredding and crushing equipment can actualy achieve that level. In the Preamble to the Part 264 promulgation, EPA has asked for data and may propose a change at a later time.

II. Classification

The regulations proposed today are Interim Status Part 265 conforming changes to the Part 264 permitting standards promulgated elsewhere in today's **Federal Register.** Considering the magnitude of the costs and impacts of the promulgated regulations, the Agency does not believe these proposed requirements will result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or in domestic or export markets. Therefore, EPA does not expect today's proposed rule to be subject to the major rule provisions of Executive Order 12291 and, therefore, does not believe that a regulatory impact analysis is necessary.

The proposed rules might have a significant impact on small entities, however, thereby triggering the requirements of the Regulatory Flexibility Act. As part of the Regulatory Flexibility Analysis being conducted for the Part 264 permitting regulations promulgated today, EPA will consider the impact of these proposed rules on small entities. The results of that analysis will be available for review,

prior to any action to finalize these proposed rules. In performing this analysis EPA will determine in more detail the costs to the economy of the proposal and, if necessary, perform a regulatory impact analysis.

The certification requirements of proposed §§ 265.222(b) and 265.229(b) are subject to the OMB clearance requirements of the Paperwork Reduction Act of 1980.

This proposal was submitted to the Office of Management and Budget for review as required by Executive Order 12291 and the Paperwork Reduction Act.

III. Request for Comment

EPA invites comments on all aspects of the proposed rule. All comments should be addressed to the Docket Clerk (see Addresses above) and should prominently bear the notation: "Docket 3004—Land Disposal Interim Status Proposal". All comments should contain specific documentation in their support.

Lists of Subjects in 40 CFR 265

Hazardous materials, Packaging and containers, Reporting and record-keeping requirement, Security measures, Surety bonds, Waste treatment and disposal, Water supply.

Dated: July 9, 1982.

Anne M. Gorsuch,

Administrator.

For the reasons set out in the preamble, Part 265, Subparts K and N, of Title 40 of the Code of Federal Regulations are proposed to be amended as follows.

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for Part 265 reads as follows:

Authority: Sections 1006, 2002(a), and 3004 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6905, 6912(a), and 6924).

2. In 40 CFR 265, Subpart K, §§ 265.222, 265.228, and 265.229 are revised to read as follows:

§ 265.222 General operating requirements.

(a) A surface impoundment must maintain enough freeboard to prevent any overtopping of the dike by overfilling, wave action, or a storm. There must be at least 60 centimeters (two feet) of freeboard.

(b) A freeboard level less than 60 centimeters (two feet) may be maintained if the owner or operator obtains certification by a qualified engineer that alternate design features or operating plans will, to the best of his knowledge and opinion, prevent overtopping of the dike. The certification, along with a written identification of alternate design features or operating plans preventing overtopping, must be maintained at the facility.

§ 265.228 Closure and post-closure care.

(a) At closure, the owner or operator must:

(1) Remove or decontaminate all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate, and manage them as hazardous waste unless § 261.3(d) of this chapter applies; or

(2)(i) Eliminate free liquids by removing liquid wastes or solidifying the remaining wastes and waste residues;

(ii) Stabilize remaining wastes to a bearing capacity sufficient to support final cover; and

(iii) Cover the surface impoundment with a final cover designed and constructed to:

(A) Provide long-term minimization of the migration of liquids through the closed impoundment;

(B) Function with minimum maintenance;

(C) Promote drainage and minimize erosion or abrasion of the cover;

(D) Accommodate settling and subsidence so that the cover's integrity is maintained; and

(E) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present.

(b) In addition to the requirements of § 265.117, during the post-closure care period, the owner or operator of a surface impoundment in which wastes remain after closure in accordance with the provisions of paragraph (a)(2) of this section must:

(1) Maintain the integrity and effectiveness of the final cover, including making repairs to the cover as necessary to correct the effects of settling, subsidence, erosion, or other events;

(2) Maintain and monitor the ground-water monitoring system and comply with all other applicable requirements of Subpart F of this part; and

(3) Prevent run-on and run-off from eroding or otherwise damaging the final cover.

§ 265.229 Special requirements for ingnitable or reactive waste.

Ignitable or reactive waste must not be placed in a surface impoundment, unless:

(a) The waste is treated, rendered, or mixed before or immediately after placement in the impoundment so that:

(1) The resulting waste, mixture, or dissolution of material no longer meets the definition of ignitable or reactive waste under §§ 261.21 or 261.23 of this chapter; and

(2) Section 265.17(b) is complied with; or

(b)(1) The waste is managed in such a way that it is protected from any material or conditions which may cause it to ignite or react; and

(2) The owner or operator obtains a certification from a qualified chemist or engineer that, to the best of his knowledge and opinion, the design features or operating plans of the facility will prevent ignition or reaction; and

(3) The certification and the basis for it are maintained at the facility; or

(c) The surface impoundment is used solely for emergencies.

3. In 40 CFR 265, Subpart N, §§ 265.310 and 265.315 are revised to read as follows:

§ 265.310 Closure and post-closure care.

(a) At final closure of the landfill or upon closure of any cell, the owner or operator must cover the landfill or cell with a final cover designed and constructed to:

(T) Provide long-term minimization of migration of liquids through the closed landfill;

(2) Function with minimum maintenance;

(3) Promote drainage and miminmize erosion or abrasion of the cover;

(4) Accommodate settling and subsidence so that the cover's integrity is maintained; and

(5) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present.

(b) After final closure, the owner or operator must comply with all post-closure requirements contained in §§ 265.117–265.120 including maintenance and monitoring throughout the post-closure care period. The owner or operator must:

(1) Maintain the integrity and effectiveness of the final cover, including making repairs to the cover as necessary to correct the effects of settling, subsidence, erosion, or other events.

(2) Maintain and monitor the ground-water monitoring system and comply with all other applicable requirements of Subpart F of this part;

(3) Prevent run-on and run-off from eroding or otherwise damaging the final cover; and

(4) Protect and maintain surveyed benchmarks used in complying with § 265.309.

§ 265.315 Special requirements for containers.

Unless they are very small, such as an ampule, containers must be either:

(a) At least 90 percent full when placed in the landfill; or

(b) Crushed, shredded, or similarly reduced in volume to the maximum practical extent before burial in the landfill.

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federal register

Monday
July 26, 1982

Part III

Department of Health and Human Services

Health Care Financing Administration

Medicare Program; Medicare Supplemental Policies

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 401, 402, 403 and 404

Medicare Program; Medicare Supplemental Policies

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This rule establishes a Federal program of certification of Medicare supplemental health insurance policies (Medicare supplemental policies) that insurers voluntarily submit for review. This rule implements requirements of section 507 of the Social Security Disability Amendments of 1980.

HCFA will administer the Federal certification program. This program goes into effect July 1, 1982, and will apply only to policies issued in those States that do not have in effect a program for regulating Medicare supplemental policies equal to or more stringent than the one established under the law. A Supplemental Health Insurance Panel, consisting of the Secretary or a designee and four Commissioners or Superintendents of Insurance appointed by the President, determines the adequacy of a State's program in relation to the standards contained in the statute.

These regulations: (1) Set standards for the certification of policies voluntarily submitted to HCFA, (2) establish procedures for the certification program, and (3) specify requirements regarding submittal of loss ratio data to HCFA for review.

DATES: These regulations are effective July 1, 1982. In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), the reporting or recordkeeping provisions that are included in this final rule in §§ 403.232 and 403.239–403.258 will be submitted for approval to the Office of Management and Budget (OMB). They are not effective until OMB approval has been obtained and a notice to that effect has been published in the **Federal Register.**

Although these regulations are final, we are providing for an additional comment period for 42 CFR 403.256, concerning loss ratio information that must accompany a policy sent to HCFA for review, because the provisions of this section were not specified in detail in the notice of proposed rulemaking. To assure consideration, comments should be received by August 25, 1982. We will publish a notice in the **Federal Register** giving the status of the OMB review and of review of the comments received. (See the supplementary information for a further discussion of the effective date of these regulations.)

ADDRESS: Address comments in writing to: Administrator, Health Care Financing Administration, Department of Health and Human Services, P.O. Box 17073, Baltimore, Maryland 21235.

If you prefer, you may deliver your comments to Room 309–G Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, D.C., or to Room 789, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Please refer to BPP–91–FC. Agencies and organizations are requested to submit comments in duplicate. Comments will be available for public inspection, beginning approximately two weeks after publication, in Room 309–G of the Department's office at 200 Independence Ave., S.W., Washington, D.C. 20201 on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (202–245–7890).

FOR FURTHER INFORMATION, CONTACT: Thomas Hoyer, 301–594–9446.

SUPPLEMENTARY INFORMATION:

I. Medicare and Private Insurance to Supplement Medicare

Medicare is a Federal health insurance program, provided for under title XVIII of the Social Security Act, for people 65 and older the some people under 65 who are disabled. The Medicare program consists of two parts, a Hospital Insurance Program (Part A) and a Supplementary Medical Insurance Program (Part B). The Medicare program was never designed to cover the total cost of providing medical care for its beneficiaries. Both Parts A and B have deductible and coinsurance cost sharing provisions. Also, there are a number of items not covered under either of Medicare's two insurance programs, such as custodial nursing home care, dental care, and eyeglasses. Beneficiaries must pay the full cost of these services out-of-pocket or may choose to purchase additional private insurance protection to help pay the costs.

About two-thirds of Medicare beneficiaries have purchased private health insurance in order to obtain assistance in meeting health care expenses not covered by the Medicare program. The policies they purchase are commonly referred to as Medicare supplemental or "Medigap" policies and principally include Medicare supplemental policies, indemnity policies, and specified disease policies.

Over the past ten years, investigations and studies by Congressional committees, the Federal Trade Commission, the news media, and various other individuals and agencies have revealed certain problems with Medigap insurance. Some of the problems relate to the nature of the policies, and some of them relate to the manner in which they are sold:

1. There is such a wide variety of Medigap policies that it is difficult, if not impossible, for a beneficiary to compare them and effectively assess their relative benefits and costs.

2. The policies themselves are often written in complicated language that obscures the extent of their coverage or the nature of their exclusions. For example, many policies contain clauses which limit or exclude payment for services received in connection with medical conditions which were known to exist at the time the policy was sold. These pre-existing condition clauses can negate coverage described in other portions of the policy.

3. It is also virtually impossible for Medicare beneficiaries to determine the value of the policy's benefits in relationship to the premiums paid. This relationship, known as the loss ratio, is a way of determining how much of the aggregate premium income from a policy an insurance organization returns in aggregate benefits. Some policies return 80 to 90 cents, or more, on the premium dollar, while other policies have been reported to return less than 25 cents.

4. Elderly beneficiaries tend to rely on insurance agents for information about the Medicare program and the coverge available under the Medigap policies they are offered, and they are particularly vulnerable to misrepresentation and other abuses. Evidence of fraud, forgery, and intimidation has been uncovered.

II. Legislation of Health Insurance and Related Initiatives

A. NAIC Activities

There have been several significant initiatives in recent years to address the problems associated with Medigap policies. The National Association of Insurance Commissioners (NAIC), an association of the chief executive officers for the regulation of insurance of the 50 States, the District of Columbia, Guam, Puerto Rico, American Samoa, and the Virgin Islands, has played a major role in the effort. The NAIC provides model laws and regulations that are adopted by many States as the

basis for the regulatory programs for insurance that is marketed within their borders. In 1979, the NAIC amended its model standards for individual accident and sickness insurance policies to include specific standards that States can use to regulate Medicare supplemental policies (Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act, as it applies to Medicare supplemental policies, hereafter referred to as "NAIC Model Standards"). The amended model, adopted by the NAIC on June 6, 1979, contains minimum standards for policies and addresses such issues as minimum coverage requirements, limits on exclusions of coverage because of pre-existing conditions, disclosure requirements, and refund requirements.

Also the NAIC, in collaboration with HCFA, developed a "Guide to Health Insurance for People with Medicare". Over six million copies of the pamphlet have thus far been distributed through social security offices, insurance companies, State insurance departments, and senior citizen interest groups.

B. Federal Legislation

In an effort to address the abuses associated with Medigap policies, Congress enacted section 507 of Pub. L. 96–265 (the Social Security Disability Amendments of 1980). That section of the law encouraged States which had not done so to establish regulatory programs that meet specified minimum standards for Medicare supplemental policies, and established a Federal voluntary certification program for Medicare supplemental policies issued in States whose programs do not meet specified standards (section 1882 of the Social Security Act (42 U.S.C. 1395ss)). (The voluntary certification program, as provided for in section 1882 of the Act and these regulations, addresses only Medicare supplemental policies, and not the other types of policies sold to Medicare beneficiaries, that is, limited benefit health insurance, indemnity, and specified disease policies.) The intent of the legislation is to assist Medicare beneficiaries in identifying Medicare supplemental policies for purchase that are represented accurately both by sales agents and promotional literature, do not duplicate Medicare or other health insurance coverage, and provide fairly priced minimum protection against health care expenses that are not paid for by Medicare.

In the debate that preceded enactment of Pub. L. 96–265, and in the law itself, Congress recognized the progress already made by the States in the area of Medigap regulation. Further, it recognized and chose not to alter the traditional role of the States in regulating insurance. Its intention in developing Federal legislation was to provide the States and insurance industry with an incentive to speed up their activities to improve the regulation and quality of Medicare supplemental policies. At the same time, Congress established an alternative mechanism—the voluntary certification program—that could be implemented at the national level for policies issued in those States that have not established or cannot be expected to establish specified regulatory programs by July 1, 1982.

While the law relies on improved State regulation of Medicare supplemental policies and the new Federal program as a major means of identifying and curbing abuses in the sale of those policies, it also places strong reliance on consumer education as a force in improving the general quality of policy offerings. The presumption is that beneficiaries, assisted by information provided by HHS, the States, insurance companies and other sources, will become better informed purchasers of insurance to supplement Medicare and that insurance organizations will therefore improve the quality of the policies they offer for sale in order to retain their competitive position in the market.

The basic provisions of section 1882 of the Act addressed in these regulations are as follows:

1. The statute mandates that the Secretary of HHS establish a voluntary program of review of Medicare supplemental policies, and of certification of those policies that meet or exceed requirements specified in the statute and implemented through these regulations. The Secretary's program is voluntary in that it provides for review of only those policies that are voluntarily submitted by insurers (section 1882(a) of the Act). It goes into effect July 1, 1982. (The Secretary has determined that HCFA will administer the voluntary program.)

2. Policies must meet the applicable NAIC Model Standards, as amended and adopted by the NAIC on June 6, 1979, and certain additional standards specified below in item 3, in order to be certified in the Secretary's program. (The NAIC has standards applicable to the full range of individual health insurance policies sold to the elderly, including Medicare supplemental policies, indemnity policies, and specified disease policies. However, it is important to note that Congress incorporated the NAIC Model Standards into the Act only to the extent that those standards specifically address "Medicare supplemental policies" as defined in section 1882(g) of the Act.)

3. Congress structured the voluntary program so that it would extend the NAIC Model Standards to certain group policies as well as individual policies. It also established minimum loss ratio requirements for each category of policy (section 1882(c) of the Act).

4. The Secretary's voluntary certification program will apply only to policies issued in those States that have not established, under State law, a regulatory program that applies standards equal to or more stringent than those specified in the statute (section 1882 (b) and (i) of the Act). It should be noted that Congress did not intend to encourage States to limit their regulatory programs to the minimum level specified in the law. On the contrary, the intent of Congress was to encourage States to implement regulatory programs that they determine are appropriate to their particular needs and to assure States that those programs meeting or exceeding specified minimum standards would be approved by a panel, as specified below. (See H.R. Rep. No. 96–944, 96th Congress, 2d Session 76–77 (1980).)

5. The statute also provides for a Supplemental Health Insurance Panel that will determine whether or not State regulatory programs for Medicare supplement policies meet the requirements of the law. The Panel consists of the Secretary or a designee, who serves as chairperson, and four State Commissioners or Superintendents of Insurance, appointed by the President (section 1882(b) of the Act).

6. The Secretary will authorize the use of an emblem by an insurer to indicate that a policy has been certified as meeting the standards of the voluntary certification program (section 1882(a) of the Act).

The statute also contains provisions which do not require regulations. These include new criminal penalties that allow the prosecution of abusive companies and agents under Federal law (section 1882(d) of the Act). These penalties apply to cases in which false statements or misrepresentations are made about a policy's certification or about the extent and nature of the policy's benefits (including economic value) for the purpose of obtaining certification. They also apply to cases of misrepresentation by an insurance agent that he or she is an employee or agent of the Federal government (for example, of the Medicare program), and to cases in

which an individual sells a policy that is known to be duplicative of Medicare coverage or other health insurance the individual has but that will not pay duplicative benefits. There is also a penalty governing the use of the mails for the advertisement, solicitation, offer for sale, or delivery of certain Medicare supplemental policies that have not been approved for sale in a State.

Section 1882(f) of the Act requires the Secretary to undertake a comprehensive study of the comparative effectiveness of various State regulatory approaches in (a) limiting marketing and agent abuse, (b) assuring the dissemination of information to Medicare beneficiaries (and to other consumers) that is necessary for informed purchase of health insurance policies, (c) promoting policies that provide reasonable economic benefits for the insured, (d) reducing the purchase of unnecessary duplicative coverage, (e) improving price competition, and (f) establishing effective State regulatory programs. At the same time, the Secretary's study must consider the need for standards for, or certification of, health insurance policies, other than Medicare supplemental policies, sold to Medicare beneficiaries.

The Secretary is also required to submit to Congress, no later than July 1, 1982, and at least every two years thereafter, a report evaluating the effectiveness of the certification procedures and the criminal penalties established under the law (section 1882(f)(2) of the Act). The report must include an analysis of the impact that the certification program and the penalties have on the types, market share, value, and cost of policies certified by the Secretary. The report will also address whether the certification program and the criminal penalties should be continued or changed.

Finally, section 1882(e) requires that the Secretary furnish all Medicare beneficiaries information that will enable them to make informed choices when purchasing Medicare supplemental policies. Before the enactment of this provision, HCFA's Office of Beneficiary Services began distributing informational materials and conducting training classes for, and issuing training materials to, individuals who have contact with Medicare beneficiaries on the State and local levels. Trained individuals are then in a position to inform beneficiaries about problems inherent in the selection of health insurance and about the certification program. HCFA will continue these activities as part of its ongoing program to assist Medicare beneficiaries in making more informed decisions about the purchase of insurance to supplement Medicare.

III. Notice of Proposed Rulemaking

In order to develop regulations for administration of the Federal certification program, we published a notice of proposed rulemaking (NPRM) in the **Federal Register** on January 21, 1981 (46 FR 6296). Because the statute is clear in most respects, the NPRM to a great extent reiterated the provisions that are contained in section 1882 of the Act. That is, the NPRM contained the following provisions:

1. Federal regulations would not affect the right of a State to regulate policies marketed in that State.

2. A Medicare supplemental health insurance policy would mean a health insurance policy or other health benefit plan that a private entity offers a Medicare beneficiary, and that provides payment for expenses not reimbursed under Medicare. This definition would apply to both individual policies and to group policies. However, group policies of employers, labor organizations, and, under certain circumstances, professional, trade, and occupational organizations would be excluded. The definition would also exclude any policy or plan of a professional, trade, or occupational association if the association (a) is composed of individuals all of whom are actively engaged in the same profession, trade, or occupation; (b) has been maintained in good faith for a purpose other than obtaining insurance; and (c) has been in existence for at least two years before offering a Medicare supplemental health policy. These exclusions are in accordance with section 1882(g) of the Act and the Conference Committee Report on H.R. 3236 (H.R. Rep. No. 96–944, 96th Congress, 2nd Session 77 (1980)).

3. In order to be certified under the voluntary program, we would require that policies meet the following conditions:

a. Policies must meet applicable State requirements.

b. Policies must meet or exceed the NAIC Model Standards identified in the law.

c. Policies must have or must be expected to have a loss ratio of 75 percent in the case of group policies, and 60 percent in the case of individual policies. We would require a qualified actuary to submit loss ratio determinations that are calculated according to specifications in the regulations.

d. The above conditions could be met by two or more policies issued in conjunction with one another in the case of a nonprofit hospital association or a medical service association, but they would have to be met by a single policy in all other cases.

4. Certified policies could bear an emblem approved by HHS where not prohibited under applicable State law. If a policy displaying the emblem were to lose certification, the insurer would have to inform policyholders of that fact within 60 days.

5. A Supplemental Health Insurance Panel (Panel) would assess State programs for regulating Medicare supplemental policies and determine whether they meet minimum standards.

6. A State would have an approved regulatory program if the Panel determines that the State has established a program under State law that applies standards, to all Medicare supplemental policies issued in that State, that are equal to, or more stringent than, the standards Congress established for the voluntary program.

7. The Federal certification program would not apply to policies issued in States with approved programs.

8. Policies issued in States with approved programs would be deemed certified, and HCFA would authorize the State to permit imprinting the emblem on them.

9. HCFA would administer the voluntary certification program. The proposed regulations set forth the following procedures with respect to certification:

a. HCFA review of policies that insurers voluntarily submit and certification of policies that meet the requirements specified above.

b. Submittal of required documentation by insurers both for initial certification and annual review.

c. Authorization given by HCFA to insurers to imprint the emblem on certified policies.

d. HCFA decertification of policies that do not meet the requirements of the regulations.

e. Administrative review, if requested by an insurer, when HCFA determines not to certify or to decertify a policy.

f. HCFA notice to all States regarding its decisions to certify or decertify policies.

g. Transfer of policies from a State program to the voluntary certification program when the Panel determines that the State's program for regulating policies no longer meets the requirements of the law.

We received comments on the proposed rule from 25 sources, including

insurance organizations, State insurance officials, medicare beneficiaries, group health associations, consumer advocates, and professional associations and organizations, such as the American Academy of Actuaries and the Health Insurance Association of America. We also received comments from fifteen actuaries in response to a special solicitation of comments on the loss ratio provisions discussed below in "Discussion of Loss Ratio Provisions".

IV. Summary of Changes in the Final Rule

After consideration of the comments, we have made the following changes from the proposed regulations. Our reasons for each change are given below in the discussion of the significant comments:

1. The definition of a Medicare supplemental policy has been revised in two ways. The definition now follows the NAIC Model regulation's wording and it applies to individuals who are eligible for Medicare by reason of age. Also, Medicare supplemental policies do not includes policies issued to employees, or to members of labor organizations, as additions to franchise plans in existence before a specified date. (Those policies are discussed in detail below in section V.A., "Definition of Medicare Supplemental Policy".)

2. The emblem will be used only by the Federal voluntary certification program, not by States with programs approved by the Panel, as provided in the NPRM.

e. The supplementary loss ratio information that insurers must submit to HCFA for review has been revised as follows:

a. Loss ratio supporting data are specified. For example, the insurer must indicate the age of beneficiaries at the time of purchase of a policy.

b. The final rule contains a list of loss ratio assumptions, such as morbidity and mortality, that the insurer must account for in the loss ratio calculations.

c. The submittal of material for annual review of a previously certified policy has been simplified. For purposes of the annual review, the insurer is required to submit only the material that has changed since the last review.

4. We have deleted the administrative procedures for the transfer of policies from a State program to the voluntary program when the Panel determines that a State ceases to have an approved program.

V. Discussion of Comments Regarding the Proposed Rule

A. Definition of Medicare Supplemental Policy

Comment 1: Representatives of Health Maintenance Organizations (HMOs) and Group Practice Prepayment Plans (GPPPs) noted that the proposed regulations would have excluded their group health plans because the statutory and regulatory language speaks to provision of reimbursement for services rather than provision of services. The commenters requested that regulations be amended to allow for the manner in which they finance and provide for services. They maintain that they could suffer a competitive disadvantage if they cannot display the emblem on their policies.

Response: As the major commentors recognized, the regulation's exclusive focus on insurance policies derives from the language in the statute and the NAIC model regulation which it incorporates by reference. The two major statutory obstacles to including HMOs are as follows. First, section 1882(g)(1) of the law defines a "Medicare supplemental policy", in part, as a policy or health plan that provides *reimbursement* for services incurred. HMOs do not meet that definition since they contract to provide *services* rather than reimbursement for them. Further, HMOs would not be able to meet the explicit loss ratio requirements in section 1882(c) because they do not value their benefits in terms of loss ratios.

We recognize that the ability of HMOs to obtain certification of their benefit plans under the voluntary program could be desirable from a marketing standpoint. We are sensitive to the concerns these organizations have expressed and we are continuing to consider the problem.

We note, however, that HMOs can already advertise themselves as Federal or State qualified under existing laws (see 42 U.S.C. 300e). Also through the publication, the "Guide to Health Insurance for People with Medicare", and its National Medigap Training Program, HCFA seeks to provide a good description of the comparative benefits of Medicare supplements, catastrophic or major medical expense policies, and HMOs. The guide is made available, in English and Spanish, free of charge, to Medicare beneficiaries and concerned individuals; and persons wishing a copy should contact their local Social Security office, by phone or mail, or in person. The training program is conducted for individuals who have contact with Medicare beneficiaries on the State and local levels.

Comment 2: An insuring organization noted that there are various lines of health insurance policies, including major medical, basic hospital, and basic medical/surgical policies that are intended primarily for the non-Medicare population. However, these policies are sometimes offered to an individual eligible for Medicare because they contain provisions that coordinate their benefits with other primary payers, including Medicare. The proposed regulations conditioned the definition of a Medicare supplemental policy, among other things, on the fact that the policy is *offered* to a person eligible for Medicare. This provision in the NPRM would have required a State program to regulate all of these policies in order to be approved by the Panel. The commenter recommends that the definition of "Medicare supplemental policy" adopt the terminology of NAIC Model Standards. Those standards specify that the policy is *designed primarily*, or is *advertised, marketed*, or *otherwise purported*, to supplement Medicare (NAIC Model Standards, section 7,I).

Response: We accept this recommendation. Because both the statute and these regulations incorporate by reference the NAIC Model Standards, we believe it is appropriate to use clarifying terminology and phraseology from those standards, when possible.

Comment 3: A consumer advocacy group suggested that the definition of Medicare supplemental policy be expanded to include any policy sold to any person, if the policy is designed and marketed primarily to supplement Medicare *when and if* that person becomes a Medicare beneficiary. The group reasons that, in exchange for higher premiums while the insured is still working, the insurer may promise lower premiums and better coverage after Medicare beneficiary status is achieved. Certification would assist the consumer in evaluating the policies.

Response: There is nothing in the statute or these regulations prohibiting the individual from applying for, or an insurer from offering, the policy. However, these regulations provide for review and certification of policies issued under a conversion privilege, as discussed below, in "Comment 4".

Comment 4: One commenter pointed out that the NAIC Model Standards (section 3) state that the Model does not apply to individual policies or contracts issued under a conversion privilege of a group or individual policy or contract, when the basic policy or contract includes provisions that are inconsistent

with the requirements of the Model. (The privilege allows the individual to purchase a Medicare supplemental policy, without being subject to the regular underwriting procedures, when the individual becomes eligible for Medicare.) Moreover, the Model does not apply to policies issued to employees, or to members of labor organizations, as additions to franchise plans in existence on the effective date of the State regulations that incorporate the NAIC Model Standards. (A franchise plan is an agreement between the insurer and the employer and employees of the same entity. Under this agreement, the insurer offers the same individual health policy to all employees. The advantage of this arrangement is that group underwriting procedures are followed, such as a waiver of the medical examination that is ordinarily required for individual policies.) The commenters suggested that final regulations should specifically exclude those conversion and additional policies or contracts.

Response: The definition of Medicare supplemental policy in 42 CFR 403.205 of this final rule (that is, a policy sold primarily for the purpose of supplementing Medicare) does not include policies whose only reference to Medicare is that they contain a conversion or coordination of benefit clause that enables the policyholder to purchase a Medicare supplement. We believe, however, that the definition should apply to policies sold to policyholders who exercise the conversion privilege. We understand that the general practice of the insurance industry is to honor conversion requests by selling the beneficiary a policy that meets the terms of the conversion and is also commonly available on the market at the time the conversion is requested. We believe that it is appropriate that these latter policies be included in the definition. Therefore, we are not revising the definition of Medicare supplemental policy to exclude policies sold under a conversion privilege.

We believe that the NAIC approach to additions to franchise plans is reasonable because it recognizes that the content of the policies sold under these agreements was determined by the terms of a prior contract. Actual sales of the policies under the franchise agreement are done under the terms of the prior contract. Therefore, we include a similar provision in these regulations. We exclude additions to franchise plans from the definition of a Medicare supplemental policy—and from the obligations concurrent with such a policy—if the plan is in existence July 1, 1982, the date HCFA can begin to certify policies.

Comment 5: The proposed rule would exclude group health insurance policies of trade, professional, and occupational associations from the definition of, and requirements regarding, Medicare supplemental policies. Commenters supported the exclusion and recommended that it be extended to policies offered to former members of the associations, and not restricted to policies offered to present members. Congress intended that group health policies of professional, trade, and occupational associations should not be treated differently from group policies of employer or labor organizations (H.R. Rep. No. 96–944, 96th Congress, 2nd Session 77 (1980)). The statute specifies that group policies of employer or labor organizations are excluded from the provisions regarding Medicare supplemental policies, even if they are offered to both present and former employees or members (section 1882(g)(1) of the Act). Therefore, the exclusion provisions should apply to association group health policies that are offered to present or former members of those associations.

Response: We do not concur with this recommendation. The language of that Conference Committee Report (H.R. Rep. No. 96–944, 96th Congress, 2nd Session 77 (1980)) addresses policies that these associations offer to their *respective memberships.* We conclude, therefore, that Congress did not intend to exclude Medicare supplemental policies offered to former members of these associations from the provisions of Pub. L. 96–265.

B. State Regulation of Insurance

Comment: Commenters from the insurance industry believe that the proposed rule would have a harmful impact on State regulation of insurance, particularly on certificates. They explain, first of all, the difference between a "certificate" and a "policy". In the case of a group policy, a single master contract is issued to the holder of the group policy. Certificates, containing a description of benefits, claims procedures, etc., are issued to individuals covered under the master contract. The group policy, including the master contract and certificates, is filed and approved under the laws of the State where the group policy is issued. Even though certificates of coverage issued in one State are marketed in other States, such States generally have reciprocity provisions.

Commenters maintain that the provisions of the NPRM imply that HCFA would not permit a certificate issued under an approved master policy to bear the emblem unless each State into which the certificate is delivered specifically reviewed that certificate as a policy and authorized its sale. If so, States could be required to abrogate existing reciprocity provisions that permit them to honor the laws of the State where the master policy is issued and to expand their own regulatory procedures to include certificates issued under that master policy. Commenting further, some respondents noted that the NPRM improperly identifies a "certificate" as a "policy" and recommended that the final rule clarify the distinction between a certificate and a policy.

Response: The intent of the proposed regulations was to reflect the statutory provisions of section 1882(j) of the Act by assertng that no provisions of the regulations are intended to prohibit States from making or enforcing (within the limits of their sovereignty) laws to regulate insurance. There was no specific intention to encourage States to initiate new regulations regarding certificates or to discontinue reciprocal agreements concerning certificates marketed within their borders when the master policy is registered and approved in another State. The proposed rule was intended to make clear to organizations submitting policies for certification under the voluntary program that the Department's review and approval of a policy does not free the insurer from the need to obtain State approval under any applicable State laws before selling the policy in that State.

Because we believe that Federal regulations should clarify that State regulation of insurance is not affected, we have not deleted the provisions in question from the final rule. However, as a result of comments received and our own review, we are making several revisions:

1. The final rule clearly identifies the relationship of a certificate to a group policy by stating that a certificate is issued under a group policy.

2. The final rule requires the insurer to submit to HCFA a list of States in which the individual or group policy is "approved for sale". In the NPRM we required a list of States in which "the insuring organization is authorized to market the policy". The wording in the final rule is more in conformity with accepted terminology of the insurance industry and State insurance agencies.

3. The regulations provide that certification of a policy by HCFA must not be construed as authorizing the insuring organization to market a policy

in a State if the policy has not been approved for sale in conformance with the applicable laws of that State. The voluntary certification program will not review a policy for certification and display of the emblem before it has been approved for sale by that State.

C. General Requirements for Policies

Comment 1: In the NPRM we stated that policies issued in a State with an approved program would be "deemed certified". Commenters noted that the terms "certificate" and "deem", for purposes of State approval of a policy, have specific, technical meanings commonly accepted by the insurance industry and State insurance agencies. (In the discussion above of the difference between a policy and a certificate issued under a policy, the term "certificate" refers to one type of contract between the insurer and the insured. In this discussion, the same term is used in reference to State approval of the contract, a usage common in States and the insurance industry.)

A "certificate" is a signature affirming the validity of the material submitted to the State regulatory agency. A filing package may include several "certificates" or signatures. Many States have a statutory "deemer" provision which sets a time limit for the review and approval of policies. If a decision is not reached by the end of this period, the insurer may market the policy, subject to review at a later date by the State if the State so chooses. While the proposed Federal regulations did not use the terms "certificate" and "deem" in the way commonly accepted by the States and the insurance industry, commenters noted that the use of "deemed certified" in regulations could mislead one to believe that States review and certify policies as does the voluntary certification program.

Response: The language of the NPRM was intended to reflect the statute which provides that a policy issued in a State with an approved program "shall be deemed" to meet the NAIC standards and loss ratio requirements of the statute. (See section 1882(b)(1) of the Act.) In order to avoid any misunderstanding, however, we have revised the regulations to delete the phrase "deemed certified" when referring to policies issued in a State with an approved program. The final regulations provide that those policies are accepted as meeting the NAIC Model Standards and loss ratio requirements specified in the final rule.

Comment 2: Proposed regulations would have provided that the NAIC model standards and the loss ratio requirements must be met in a single policy, but could be met in two or more policies issued in conjunction with one another in the case of a nonprofit hospital association or a medical service association. A commenter from the NAIC suggested that we qualify the exceptions. They were provided for in the statute (section 1882 (c)(1) of the Act) for those cases where State law or regulation prohibits the inclusion of all benefits in a single policy, and it is appropriate that regulations limit the exceptions to those cases. Also, the NAIC Model Standards, defined below in this preamble, impose the same limitation on these exceptions. (See Drafting Note that follows section 7, I of the NAIC Model Standards.)

Response: We have accepted this suggestion and incorporated it into the final rule.

D. NAIC Model Standards

Comment 1: Commenters stated that the NAIC provisions apply the term "Medicare supplement policy" (which corresponds to the term "Medicare supplemental policy" as defined in section 1882 of the Act) only to a policy offered to an individual eligible for Medicare "by reason of age" (section 7, I of the NAIC Model Standards). Since the Federal statute incorporates the standards adopted by the NAIC, Federal regulations should adhere to them wherever possible. Specifically, Federal regulations should adopt the "by reason of age" limitation. Also, commenters maintained that application of these standards to policies offered to the under 65 age group (that is, those eligible for Medicare by reasons of disability) would generate administrative burdens and costs out of proportion to the benefits achieved. States would have to review more policies in order to have an "approved" program for the regulation of Medicare supplemental health insurance; and insurers would have to revise their solicitations to identify those under 65 who are eligible for Medicare (a group that insurers do not now make an effort to identify). Commenters asserted that so few policies are sold to the disabled that the costs of these efforts would exceed benefit to the public.

Response: We agree with these comments and have amended the regulations to permit the application of the NAIC definition of a Medicare supplemental policy; that is, one offered to an individual eligible for Medicare "by reason of age". In making this change, we have brought the regulatory definition into conformance with the programs of some 38 States whose regulations embody this principle of the NAIC model. The broader definition contained in the NPRM is inconsistent with the interpretations of the majority of the States and retaining it would discourage the wide State cooperation and support that the Congress hoped to elicit through the Medigap provision.

Comment 2: In the preamble to the NPRM, we had summarized the provisions of the NAIC Model Standards, for the convenience of the readers of the proposed rule. In that summary, we noted that, under the NAIC standards, policies must provide for coverage of 20 percent of Medicare eligible expenses under Part B, subject to a maximum calendar year out-of-pocket deductible of $200 of such expenses. (See section 7, I (2)(d) of the NAIC Model Standards.) Commenters asked if the $75 annual Medicare deductible is to be included in the $200 NAIC standards deductible. (Part B of Medicare has an annual deductible that is adjusted periodically by legislative mandate. For 1982, this deductible is $75.)

Response: The $75 deductible is included in the calculation of the $200. The intent of the NAIC model is that the individual not be required to pay more than $200 out-of-pocket for Medicare eligible expenses under Part B. Not to include the $75 Medicare deductible would subject the individual to a $275 out-of-pocket expenditure.

We wish to note at this point that we are not publishing a summary of the NAIC Model Standards in this final rule, as we did in the NPRM. To ensure complete accuracy, we believe that concerned parties should rely on the complete, official text, rather than on a summary which, however carefully prepared, will necessarily suffer from compression and the absence of complete cross-references to other NAIC model laws and regulations. Complete copies of the NAIC Model Standards may be obtained from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 West Franklin Avenue, Minneapolis, Minnesota 55404.

E. The Emblem

Comment 1: Several commenters representing both sellers of insurance and regulators of insurance noted that section 1882(a) of the Act provides that the Secretary is to authorize the use of the emblem specifically on policies that have been certified under the voluntary program. In other words, the emblem is an integral part of the voluntary program and should be displayed only

on policies that are appoved by HCFA under that program. Commenters are also concerned that the Secretary will have limited control over State use of the emblem, and that some insurers would tend to use it to give a "government look" to their policies. Therefore, the commenters recommend that regulations be revised so that States with approved programs not be permitted to authorize the use of the emblem on policies issued under their jurisdictions.

Response: In the NPRM we proposed that States use the emblem to enable beneficiaries in States with approved programs to identify policies that meet the standards of these regulations. Also, we believe that Federal monitoring would ensure its proper use in those States. However, we concur with the comments and the final rule provides that the emblem will be used only by the Federal voluntary certification program.

Comment 2: In the case of a policy displaying the emblem, the proposed rule would require the insurer to notify each policyholder, in writing, within 60 days of the loss of certification. Five consumer groups supported this provision, but they suggested that the time period is too lenient. They also noted that, in the case of a policy that should lose certification, for example, for failing to meet loss ratio requirements, the insurer could continue to market that policy for over four months while the insurer requests and receives an administrative review. (That period covers the following steps: The insurer has one month to appeal an HCFA decision to decertify a policy, and HCFA has three months to initiate and complete a review of material submitted for a reconsideration. If HCFA's final decision were to decertify the policy, the determination would go into effect in 15 days.)

Other commenters did not support this provision of the proposed rule and recommended that it be deleted. They maintain that such a notice would create an environment for hasty replacements and generate confusion and alarm among the policyholders. As an option, they suggested that a notice not be required when loss ratios fall below the required level, but only that the insurer be prohibited from selling additional policies as certified.

Response: Congress clearly intended that the emblem be displayed on condition that the insurer agree to notify policyholders of the loss of certification when the Secretary determines that the policy no longer satisfies the standards and requirements of the voluntary certification program (H.R. Rep. No. 96–944, 96th Congress, 2nd Session 76 (1980)). The proposed rule reflects the intent of Congress. For that reason, and because we think beneficiaries who purchased policies on the strength of their certification clearly are entitled to know when that certification ends, we believe that the provision should not be deleted. However, to avoid undue delays in final decisions while still allowing sufficient opportunity for review, we are providing that HCFA must initiate and complete the review within 90 days of the HCFA notice that the policy is losing certification or is not being certified by HCFA.

We acknowledge that potential misunderstandings can arise from the notification process. For example, a policy can lose certification because it fails to meet loss ratio requirements; and the policyholder might interpret this to mean that the policy no longer provides for certain benefits. Therefore, we have revised the notification process. The insurer must send the notice of loss of certification in the next regular premium notice to the policyholder, but not later than 60 days after the policy loses certification. The first option enables the insurer to avoid a special mailing, while the second option guarantees the insurer at least 60 days to inform policyholders if the loss of certification occurs just before the insurer planned to send the premium notice.

Finally, these regulations require that the insurer notify the policyholder if the policy was marketed as a certified policy, whether or not it displays the emblem. Moreover, in the case of a group policy, each holder of a certificate issued under the policy and marketed as "certified" must be notified.

F. State With Approved Program

Comment 1: The NPRM defined the term "policy issued in that State" as a means of delineating the universe of policies to which a State regulatory program would need to apply. The term was originally defined to mean a group policy if the holder of the master policy resides in that State, and an individual policy if the holder of the policy resides in that State. Commenters noted that it is not workable to determine whether or not a policy is issued in a State by reference to the residence of the policyholder. For example, if an individual owning a policy resides in State A, and then moves to State B, it is not accurate to speak of the policy as issued in State B. Similarly, there is no existing law to prevent an individual in State A, which will not approve a given policy, from traveling to State B and purchasing the policy there. Again, it would be incorrect to speak of that policy as being issued in State A, the residence of the policyholder. Therefore, a commenter recommends that an individual policy be defined as "issued, delivered, or issued for delivery in that State" if the policy is issued in, or issued for delivery in, that State.

Response: We concur and have revised the regulations to incorporate this suggestion.

Comment 2: Several persons inquired what provisions were being made for the transfer of policies, particularly those bearing the emblem, from the Federal program to the State program when the Panel determines the State has an approved program.

Response: In the case of a policy issued in a State that has an approved program after HCFA certifies the policy, the insurer may continue to display the emblem on the policy, unless otherwise prohibited by the State law or regulation. However, the insurer may continue to do so only until the date that the insurer would have had to submit material to HCFA for review in order to retain certification in the absence of a State program. We believe that this provision is appropriate. The intent of the emblem is to identify a policy that meets specified standards, and has been so certified by HCFA. The fact that the policy is now issued in a State that has an approved program assures that the policy continues to meet those standards. To obligate the insurer to cease using the emblem immediately, in the absence of restrictive State regulations, could confuse policyholders unduly and create an unnecessary financial burden for the insurer.

Finally, HCFA will inform the public, through its continuing education and training programs, which States have approved programs. This is particularly important information when an individual is considering a policy not certified by HCFA. If that policy is issued in a State with an approved program, the buyer can assume that the policy at least meets the minimum requirements specified in these regulations.

G. Submittal of Data to HCFA for Review to Obtain or Retain Certification

Comment: The NPRM would have required the insurer, for purposes of the annual review, to resubmit all of the material that was submitted for the previous year's certification, recertification (after a loss of certification), or annual review. Commenters suggested that the insurer should submit only that material that has changed since the last submittal. Commenters noted that no purpose is

served by the insurer's resubmittal of material that HCFA already has on file.

Response: In response to the above comments, we have simplified the refiling requirements. The final regulations provide that the insurer needs to submit only the following for the annual review:

a. Loss ratio information, regarding past experience, specified below in "Loss Ratios: Supporting Actuarial Data".

b. Material that has changed since the last submittal, for example, changes in benefits.

c. A statement, signed by the company president or designee, to confirm that the material is accurate and that the policy continues to meet the requirements of the regulations.

H. Decertification of Policies

Comment: The NPRM described HCFA as decertifying a certified policy that fails to continue to meet specified standards. Some insuring organizations maintain that HCFA does not "decertify" a policy; rather, the policy "loses its certification". They maintain that the law authorizes the Secretary only to certify a policy, not to decertify it.

Response: Certification shows that a policy meets specified standards and that the policy may display the emblem signifying HHS certification. Sound management of the voluntary certification program requires that all concerned parties know when a policy that has been sold as "certified" ceases to have that status. (Also, section 1882(d) of the Act provides for Federal penalties in cases where an individual makes a false statement regarding the use of the emblem, which is authorized for use only on certified policies.) For this reason, the NPRM provided for a clearly identifiable point in time when a policy ceases to be certified—when HCFA decertifies a policy. We also chose this term based on reasoning that, since the statute gives the authority to "certify" a policy, the statute implicitly gives the authority to "decertify" that policy if it ceases to meet specified requirements.

In the light of the comments, however, we have revised the regulations to provide for "loss of certification", rather than for "decertification". "Loss of certification" occurs when a policy ceases to meet the requirements for certification under the voluntary program. This can occur either when the insurer chooses not to continue to meet the requirements or when HCFA determines that the policy fails to meet the requirements.

J. Termination of a State Program

The proposed rule contained detailed provisions for the transfer of policies from State jurisdiction to the voluntary certification program in cases where the Panel determines that the State ceases to have an approved program of its own for regulating policies. Our concern was to provide for an orderly transfer of policies that display the emblem, without undue burden on the insurer and without confusing the policyholders. Because these final rules do not authorize States with approved programs to use the emblem, we have deleted the provisions regarding transfer of policies from the final rule. We note, however, that when the Panel determines that a State ceases to have an approved program, policies issued in that State may be submitted for review under the Federal voluntary program.

VI. Discussion of Loss Ratio Provisions

A. Federal Programs and Loss Ratios

One manner of assessing the value of a policy is to determine how much of the aggregate premium income from a policy the insurer returns in aggregate benefits to the policyholders. The relationship of benefits to premiums is the loss ratio. The statute (section 1882(c) of the Act) provides the following basic guidelines regarding loss ratios:

1. A policy must be expected to return to policyholders, in the form of aggregate benefits, at least 75 percent of aggregate premiums in the case of group policies, and at least 60 percent in the case of individual policies.

2. Loss ratios are to be determined according to "accepted actuarial principles and practices".

3. Loss ratios are to be calculated for the period for which rates are computed for coverage purposes.

4. Loss ratios are to be based on incurred claims experience and earned premiums for that period.

The law, however, does not contain specific guidelines for use by actuaries who calculate loss ratios (other than that they must be calculated according to "accepted actuarial principles and practices"), or by reviewers who must determine whether or not a policy provides a minimum level of benefits in relation to premiums paid. Therefore, we believe Federal regulations must provide specifications to guide both actuaries and reviewers. Accordingly, the proposed rule included the basic guidelines contained in the law and also specified in some detail how the insurer would compute "benefits" and "premiums" for purposes of loss ratio determinations. In addition, the NPRM would have required a qualified actuary to certify the appropriateness of the loss ratio calculations. In the proposed rule, we also specifically invited comments on how the following aspects of loss ratio calculations should be provided for in the final rule:

1. The impact on premiums and benefits that is caused by the expected future change in the age and sex distribution of the insured group.

2. The impact of screens used to select the insured and to exclude pre-existing conditions.

3. Assumptions that are made regarding a variety of factors, such as lapse of policies, interest on reserves, mortality, and morbidity.

4. Supporting data that the insurer should submit with loss ratios (for example, scale of gross premiums, a description of assumptions, formula used to calculate gross premiums, and expected level of earned premiums and incurred claims).

In addition to publishing the proposed rule, HCFA studied the practices of various States and consulted insurance and actuarial groups and other professionals in the field to develop specifications regarding loss ratios. In the course of this study, we received comments from fifteen professionals. We are including their comments, together with comments received in response to the NPRM, in the following discussion.

B. Loss Ratios: General Provisions

Comment 1: Insuring organizations commented that Federal regulations should not attempt to guide the actuary through each step of the calculations, as was proposed in the NPRM.

Response: The loss ratio formula and specific components in the NPRM embody provisions of the statute, that is, that the *expected* level of earned premiums be taken into account and that calculations be according to *accepted actuarial principles and practices.* (See section 1882(c)(2) of the Act.) The provisions of our regulations are intended to ensure that, for purposes of Federal certification, insuring organizations calculate loss ratios consistently and according to statutory requirements. Our major reason, however, for including these specifications is to provide criteria that HCFA will use to review all policies that insurers submit under the voluntary certification program, thereby assuring a consistent and equitable review of all policies.

Comment 2: Community or pool rated policies develop a premium rate for a short period of time reflecting the aggregate anticipated experience of

people insured. This rating method is distinct from the "level premium" approach that seeks to charge a rate that will be adequate on the average to cover costs over a longer term policy lifetime. Commenters recommend, therefore, that regulations specifically provide for the different ways that premium rates are calculated.

Response: In view of the comment received, we have revised the regulations to enable insurers to calculate benefits of community and pool related policies that are rerated on an annual basis in a way that conforms to the rating method specific to those policies. In order to calculate benefits, insurers are simply to determine the expected incurred benefits in the loss ratio calculation period. We have deleted the need to account for policy reserves because in the case of these policies, whose premiums are calculated for a year or less, the method that the insurer uses to account for policy reserves is not a significant variable in determining the loss ratio.

C. Loss Ratio Dates and Time Frames

Comment: The American Academy of Actuaries commented on the proposed wording of the NPRM that would enable the insurer, for purposes of calculating "present values", to use an "aggregate computed for a period not to exceed twelve consecutive months". While the intent of this provision might be to permit the actuary in the case of short term policies to ignore the potential impact of such factors as lapse of policy and survivorship on the loss ratio, it might be misconstrued to require that long-term policies have a loss ratio each year at least equivalent to the minimum loss ratio. Such a requirement is not specified in the law. On the contrary, the statute specifically refers to the loss ratio that is "estimated for the entire period for which rates are computed to provide coverage" (section 1882(c)(2) of the Act). The commenter recommended that the wording be changed to read: "Discounting may be ignored for periods not exceeding twelve months". (Discounting is the actuarial procedure that provides for the impact of such factors as lapse of policies and survivorship of policyholders on the loss ratio.)

Response: Our intent in the proposed rule was to provide assurance that in the case of one-year term policies, discounting would not be required over the one-year term period. However, we believe that the recommended wording is more appropriate and are incorporating it in the final rule.

D. Loss Ratios: Supporting Actuarial Data

Comment 1: The proposed rule would require insurers to submit the formula used to calculate gross premiums to HCFA for review. Actuaries noted that this formula is not necessary for a review of the loss ratio calculations.

Response: We concur with this comment and have deleted this requirement from the regulations.

Comment 2: The NPRM proposed that the insurer submit an actuarial certification, signed by an actuary, stating that the assumptions used in the loss ratio calculations are reasonable and appropriate. The American Academy of Actuaries and other commenters suggested that we substitute the words "statement of actuarial opinion" for the phrase "actuarial certification". They believe the term "certification" misrepresents the nature of the actuary's function by implying a level of exactness and precision that is inappropriate in this situation. On the other hand, they believe the term "statement of acturial opinion" more accurately characterizes the actuary's professional role. It is analogous to professional opinions that are issued routinely in law, medicine, accounting, and other professions.

Response: We concur with this suggestion and have revised the regulations.

E. Additional Data Requirements:

As a result of our analysis of the proposed rule, we are requiring that the insurer submit additional data that are necessary for HCFA to perform an actuarial review of the expected loss ratio to determine whether or not the policy meets the standards of the law. We believe that these are data the insurer will have available because the insurer needs them to determine a policy's benefits and premiums, and therefore no additional effort will be required to supply them. Accordingly, final regulations require the insurer to send the following information to HCFA:

1. Why the policy should be considered, for purposes of the loss ratio determination, an individual or a group policy.

2. The earliest age at which policyholders can purchase the policy.

3. The general marketing method and the underwriting criteria used for selection of applicants to whom coverage will be offered.

4. What policies are to be included under the one policy form, by the dates the policies are issued, for example, "all policies issued on or after July 1, 1981".

5. The loss ratio calculation period.

6. The scale of premiums for the loss ratio calculation period.

7. In the case of a policy submitted for recertification or annual review, details of all changes in information regarding items 1–6 above, since HCFA last reviewed the policy.

8. In the case of a policy submitted for recertification or annual review, past loss ratio experience (including the experience of all policies, riders, and endorsements issued under the policy form). The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that are calculated—

a. For all years of issue combined; and

b. Separately for each calendar year since the policy was first certified.

F. Loss Ratios: Actuarial Assumptions

In calculating loss ratios, the actuary must provide for the impact of a variety of factors (morbidity, mortality, etc.—identified as actuarial assumptions) on future benefits and premiums. The selection of assumptions and their interpretation depend to a great extent on the actuary's professional judgement. Therefore, in order to identify which actuarial assumptions are necessary for calculating and reviewing loss ratios, for purposes of the voluntary certification program, we specifically invited comments and suggestions regarding this issue.

In addition to the general request for suggestions in the NPRM, we prepared a list of actuarial assumptions, that we considered appropriate for the voluntary certification program, and sent it to actuaries for review and comment. The list included the following:

a. Morbidity.

b. Mortality.

c. Lapse.

d. Assumed increases in the Medicare deductible.

e. Impact of inflation on reimbursement per service.

f. Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

g. Expected impact on morbidity by policy duration of (1) the processes used by the insurer to select insureds from among those that apply for the policy and (2) pre-existing condition clauses of the policy.

In addition to the above listing, we also asked the actuaries to comment on a proposal that would enable actuaries to use policy reserves that are calculated in accordance with State laws and regulations, rather than according to the provisions of the NPRM. Because States wish to assure the insurers' fiscal solvency, they

generally require that insurers maintain a conservative policy reserve, generally higher than the provisions of our proposed rule would have required. Our proposal would allow the insurer to use State-mandated policy reserves, but would require the insurer to indicate this when submitting material to HCFA for review. This provision would ease the burden on insurers by enabling them to use policy reserve calculations that have already been determined to comply with State requirements, rather than calculating policy reserves specifically for purposes of the voluntary certification program. However, the insurer who used this alternate method would be required *to be capable of demonstrating* that the alternate method results in a loss ratio that is the same or lower than that obtained if the provisions of the proposed rule were used.

Comment: Commenters generally supported our intent to require that insurers submit the actuarial assumptions itemized above. However, they did recommend two revisions. First, regulations should not require the insurer "to be capable of demonstrating" that the State specifications for calculating policy reserves does not result in a higher loss ratio than the specifications provided in Federal regulations. This provision could be interpreted as mandating dual calculations by the insurer and thereby increasing the burden; therefore, it should be deleted. Second, the list of assumptions should be expanded to include interest on reserves—an item generally provided for according to accepted actuarial principles.

Response: We agree with these suggestions and have revised the regulations accordingly.

G. Confidentiality

Insurers have requested assurances that we maintain confidentiality for some of the loss ratio information that they must submit to us for review. Although the loss ratio percentages are generally available to the public, some portions of the supporting data, for example, morbidity, that the insurer uses to calculate those percentages are not public information. To reveal that data to the public could result in a competitive disadvantage or harm to the insuring organization. Insurers are concerned that under the Freedom of Information Act (FOIA) (5 U.S.C. 552), we would be obligated to share that data with a third party upon request.

Under provisions of the FOIA, "trade secrets and commercial or financial information" are exempt from release by the agency (5 U.S.C. 552(b)(4)). Accordingly, the Secretary will exempt privileged or confidential information when its disclosure would likely cause substantial harm to the submitting organization's competitive position; or when its release would impair the Department's ability to obtain similar information in the future. In the event of an FOIA request, we would review material on a case-by-case basis to determine if it falls under the exemption cited above and release only as much material as is appropriate.

H. Request for Additional Comments

These regulations, at 42 CFR 403.256, require the insurer to submit certain supplementary loss ratio information to HCFA for review. This information consists of supporting data and assumptions that the insurer used to determine the policy's loss ratio. We did not provide for this material in the proposed regulations, but we did invite comments regarding this material and state that we would provide for additional comments in the final rule. Accordingly, we are inviting comments on 42 CFR 403.256 of these final regulations; and we will publish any revisions in the **Federal Register** that are appropriate. To assure considerations, comments should be received no later than 30 days after publication of this rule.

VII. Effective Dates

1. HCFA cannot begin to certify policies until the Panel's initial determinations as to which States cannot be expected to establish programs that meet the requirements of the statute become effective. Section 1882(i) of the Act specifies that Panel's initial determinations must be submitted to Congress no later than January 1, 1982 and that they become effective 60 days later. In counting those 60 days, "days on which either House is not in session because of an adjournment sine die or an adjournment of more than three days to a day certain are excluded in the computation". (See section 1882(i)(2)(B) of the Act.) The Panel's report was transmitted by the Secretary on February 2, 1982.

The reporting or recordkeeping provisions that are included in this final rule in §§ 403.232 and 403.239–403.258 will be submitted for approval to the Office of Management and Budget (OMB). They are not effective until OMB approval has been obtained and a notice to that effect has been published in the **Federal Register.**

As previously indicated, this certification process applies only to policies issued in those States that do not have a regulatory program meeting Federal standards. If the Panel reverses an earlier negative determination, by approving the State's regulatory program, any policy that HCFA has previously reviewed, and that is issued in that State, will immediately cease to come under the voluntary certification program.

Insuring organizations wishing to submit policies subject to the Secretary's review and certification under these regulations should mail the material required under 42 CFR 403.232 to:

Voluntary Certification Program, Medigap Operations Staff, c/o Office of the Bureau Director, Bureau of Program Operations, Health Care Financing Administration, Room 500 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207

2. The earliest effective date of HCFA's certification of a policy is July 1, 1982 or later. That is also the first date that a certified policy may display the emblem or that an insurer may advertise that policy to be certified (section 1882(i) of the Act).

VIII. Impact Analyses

A. Executive Order 12291

The Secretary has determined that these interim final regulations do not meet the criteria for a major rule, as defined by section 1(b) of Executive Order 12291, because they do not have an economic effect of $100 million or otherwise meet the threshold criteria of the executive order. We expect that this rule will impose a maximum cost of approximately $125,000 on the insurance industry in meeting the filing requirements. Based on our estimate of the number of States that will be included in the voluntary certification program, we have projected that 50 companies will submit two policies each to HCFA for review. Assuming that virtually all of these companies have access to an automated data base, the estimated average cost per company for the two policies is approximately $2,500. Therefore, the total cost is about $125,000. In addition, the provisions of these regulations should stimulate competition among insurers marketing all types of policies to supplement Medicare.

B. Regulatory Flexibility Analysis

The Secretary certifies, under section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354), that the regulations proposed in this interim final rule will not have a significant economic impact on a substantial number of small entities. The reason for the Secretary's

negative certification is that only a few of the organizations that market health insurance will come under the voluntary certification program.

There are approximately 1800 organizations marketing health insurance in the United States. There are no comprehensive studies available at this time that identify the total number of organizations that market some sort of policy to supplement Medicare. However, based on comprehensive data furnished by the Federal Trade Commission on Medicare supplemental policies offered in five States, limited data furnished by the insurance industry, and additional information obtained from several States that list all organizations marketing supplemental policies, we have been able to identity 160 organizations that market supplemental policies. (However, there is no way of determining precisely how many of the organizations market policies that meet the statutory and regulatory definition of a voluntary certification program.) Of the 160 organizations, only seven are small entities, that is, independently owned and operated and not dominant in their field of operation. Among these seven, only two organizations market policies to supplement Medicare in States that we believe will come under the voluntary certification program.

IX. Response to Comments

Because of the large number of comments we receive, we cannot acknowledge or respond to them individually. However, if as a result of comments we believe that changes are needed in these regulations, we will publish the changes in the **Federal Register** and respond to the comments in the preamble of that document.

List of Subjects

42 CFR Part 403

Medicare supplemental insurance, Voluntary certification program, Medicare supplemental health insurance panel.

42 CFR Chapter IV is amended as set forth below.

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS [AMENDED]

1. The entire contents of Part 401 are transferred from Subchapter B to Subchapter A.

2. The table of contents for the chapter is amended by adding a title for Subchapter A, reserving Parts 400, 402, and 404, and adding a new Part 403 to read as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Subchapter A—General Provisions

* * * * *

3. Subchapter A is amended by adding a title, reserving Parts 400, 402 and 404, moving the entire contents of Part 401 to subchapter A from subchapter B, adding a new Part 403, reserving Subpart A of Part 403, and adding a new Subpart B of Part 403 to read as follows:

SUBCHAPTER A—GENERAL PROVISIONS

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A—[Reserved]

Subpart B—Medicare Supplemental Policies

Authority: Sections 1102, 1871, 1874(a), and 1882 of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395kk(a), and 1395ss).

§ 403.200 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, section 1882 of the Social Security Act. The intent of that section is to enable Medicare beneficiaries to identify Medicare supplemental policies that do not duplicate Medicare, and that provide adequate, fairly priced protection against expenses not covered by Medicare. The legislation establishes certain standards for Medicare supplemental policies and provides two methods for informing Medicare beneficiaries which policies meet those standards:

(1) Through a State approved program, that is, a program that a Supplemental Health Insurance Panel determines to meet certain minimum requirements for the regulation of Medicare supplemental policies; and

(2) In a State without an approved program, through certification by the Secretary of policies voluntarily submitted by insuring organizations for review against the standards.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures HCFA will use to implement the voluntary certification program.

General Provisions

§ 403.201 State regulation of insurance policies.

(a) The provisions of this subpart do not affect the right of a State to regulate policies marketed in that State.

(b) Approval of a policy under the voluntary certification program, as provided for in § 403.235(b), does not authorize the insuring organization to market a policy that does not conform to applicable State laws and regulations.

§ 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (d) of this section, "Medicare supplemental policy" (policy) means a health insurance policy or other health benefit plan—

(1) That a private entity offers to a Medicare beneficiary; and

(2) That is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) Unless otherwise specified in this subpart, the term "policy" includes both policy form and policy.

(1) "Policy form" means the form of health insurance contract that is

approved by and on file with the State agency for the regulation of insurance.

(2) "Policy" means the contract—

(i) Issued under the policy form; and

(ii) Held by the policyholder.

(c) Medicare supplemental policy includes the following:

(1) An individual policy.

(2) A group policy.

(d) Medicare supplemental policy does not include any of the following health insurance policies or health benefit plans:

(1) A policy or plan of one or more employers for employees, former employees, or any combination thereof.

(2) A policy or plan of one or more labor organizations for members, former members, or any combination thereof.

(3) A policy or plan of the trustees of a fund established by one or more labor organizations, one or more employers, or any combination, for any one or combination of the following:

(i) Employees.

(ii) Former employees.

(iii) Members.

(iv) Former members.

(4) A policy or plan of a profession, trade, or occupational association, if the association—

(i) Is composed of individuals all of whom are actively engaged in the same profession, trade, or occupation;

(ii) Has been maintained in good faith for a purpose other than obtaining insurance; and

(iii) Has been in existence for at least two years before the date of its initial offering of a Medicare supplemental health insurance policy to its members.

(5) For purposes of the voluntary certification program, a policy issued to an employee or to a member of a labor organization as an addition to a franchise plan (a plan that enables members of the same entity to purchase an individual policy marketed to them under group underwriting procedures), if the plan is in existence on July 1, 1982.

§ 403.206 General standards for Medicare supplemental policies.

(a) For purposes of the voluntary certification program described in this subpart, a policy must meet—

(1) The National Association of Insurance Commissioners (NAIC) model standards as defined in § 405.210; and

(2) The loss ratio standards specified in § 403.215.

(b) Except as specified in paragraph (c) of this section, the standards specified in paragraph (a) of this section must be met in a single policy.

(c) In the case of a nonprofit hospital or a medical association where State law prohibits the inclusion of all benefits in a single policy, the standards specified in paragraph (a) of the section must be met in two or more policies issued in conjunction with one another.

§ 403.210 NAIC model standards.

(a) "NAIC model standards" means the National Association of Insurance Commissioners (NAIC) "Model Regulation to Implement the Individual Accident and Insurance Minimum Standards Act" (as amended and adopted by the NAIC on June 6, 1979, as it applies to Medicare supplemental policies). Copies of the NAIC model standards can be purchased from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 Franklin Avenue, Minneapolis, Minnesota 55404. The NAIC model standards are also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street, N.W., Washington, D.C. 20408.

(b) The policy must comply with the provisions of the NAIC model standards, except as follows:

(1) "Policy", for purposes of this paragraph, means individual and group policy, as specified in § 403.205. The NAIC model standards limit "policy" to individual policy.

(2) The policy must meet the loss ratio standards specified in § 403.215.

§ 403.215 Loss ratio standards.

(a) The policy must be expected to return to the policyholders, in the form of aggregate benefits provided under the policy—

(1) At least 75 percent of the aggregate amount of premiums in the case of group policies; and

(2) At least 60 percent of the aggregate amount of premiums in the case of individual policies.

(b) For purposes of loss ratio requirements, policies issued as a result of solicitation of individuals through the mail or by mass media advertising are considered individual policies.

State Regulatory Programs

§ 403.220 Supplemental Health Insurance Panel.

(a) *Membership.* The Supplemental Health Insurance Panel (Panel) consists of—

(1) The Secretary or a designee, who serves as chairperson, and

(2) Four State Commissioners or Superintendents of Insurance appointed by the President. (The terms Commissioner or Superintendent of Insurance include persons of similar rank.)

(b) *Functions.*

(1) The Panel determines whether or not a State regulatory program for Medicare supplemental health insurance policies meets and continues to meet minimum requirements specified in section 1882 of the Social Security Act.

(2) The chairperson of the Panel informs the State Commissioners and Superintendents of Insurance of all determinations made under paragraph (b)(1) of this section.

§ 403.222 State with an approved regulatory program.

(a) A State has an approved regulatory program if the Panel determines that the State has in effect under State law a regulatory program that provides for the application of standards, with respect to each Medicare supplemental policy issued in that State, that are equal to or more stringent than those specified in section 1882 of the Social Security Act.

(b) "Policy issued in that State" means—

(1) A group policy, if the holder of the master policy resides in that State; and

(2) An individual policy, if the policy is—

(i) Issued in that State; or

(ii) Issued for delivery in that State.

(c) A policy issued in a State with an approved regulatory program is considered to meet the NAIC model standards in § 403.210 and loss ratio standards in § 403.215.

Voluntary Certification Program: General Provisions

§ 403.231 Emblem.

(a) The emblem is a graphic symbol, approved by HHS, that indicates that HCFA has certified a policy as meeting the requirements of the voluntary certification program, specified in § 403.232.

(b) Unless prohibited by the State in which the policy is marketed, the insuring organization may display the emblem on policies certified under the voluntary certification program.

(c) The manner in which the emblem may be displayed and the conditions and restrictions relating to its use will be stated in the letter with which HCFA notifies the insuring organization that a policy has been certified. The insuring organization must comply with these conditions and restrictions.

(d) If a certified policy is issued in a State that later has an approved regulatory program, as provided for in § 403.222, the insuring organization may display the emblem on the policy until the earliest of the following:

(1) When prohibited by State law or regulation.

(2) When the policy no longer meets the requirements for Medicare supplemental policies specified in § 403.206.

(3) The date the insuring organization would be required to submit material to HCFA for annual review in order to retain certification, if the State did not have an approved program (see § 403.239).

§ 403.232 Requirements and procedures for obtaining certification.

(a) To be certified by HCFA, a policy must meet—

(1) The NAIC model standards specified in § 403.210;

(2) The loss ratio standards specified in § 403.215; and

(3) Any State requirements applicable to a policy—

(i) Issued in that State; or

(ii) Marketed in that State.

(b) An insuring organization requesting certification of a policy must submit the following to HCFA for review:

(1) A copy of the policy form (including all the documents that would constitute the contract of insurance that is proposed to be marketed as a certified policy).

(2) A copy of the application form including all attachments.

(3) A copy of the uniform certificate issued under a group policy.

(4) A copy of the outline of coverage, in the form prescribed by the NAIC model standards.

(5) A copy of the Medicare supplement buyers' guide to be provided to all applicants if the buyers' guide is not the HCFA/NAIC buyers' guide.

(6) A statement of when and how the outline of coverage and the buyers' guide will be delivered and copies of applicable receipt forms.

(7) A copy of the notice of replacement and statement as to when and how that notice will be delivered.

(8) A list of States in which the policy is authorized for sale. If the policy was approved under a deemer provision in any State, the conditions involved must be specified.

(9) A copy of the loss ratio calculations, as specified in § 403.250.

(10) Loss ratio supporting data, as specified in § 403.256.

(11) A statement of actuarial opinion, as specified in § 403.258.

(12) A statement that the insuring organization will notify the policyholders in writing, within the period of time specified in § 403.245(c), if the policy is identified as a certified policy at the time of sale and later loses certification.

(13) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy meets the requirements specified in paragraph (a) of this section; and

(ii) The information submitted to HCFA for review is accurate and complete and does not misrepresent any material fact.

§ 403.235 Review and certification of policies.

(a) HCFA will review policies that the insuring organization voluntarily submits, except that HCFA will not review a policy issued in a State with an approved regulatory program under § 403.222.

(b) If the requirements specified in § 403.232 are met, HCFA will—

(1) Certify the policy; and

(2) Authorize the insuring organization to display the emblem on the policy, as provided for in § 403.231.

(c) If HCFA certifies a policy, it will inform all State Commissioners and Superintendents of Insurance of that fact.

§ 403.239 Submittal of material to retain certification.

(a) HCFA certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with HCFA no later than the date specified in paragraph (b) or (c) of this section:

(1) Any changes in the material, specified in § 403.232(b), that was submitted for previous certification.

(2) The loss ratio supporting data specified in § 403.256(b).

(3) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy continues to meet the requirements specified in § 403.232(a); and

(ii) The information submitted to HCFA for review is accurate and complete and does not misrepresent any material fact.

(b) Except as specified in paragraph (c) of this section, the insuring organization must file the material with HCFA no later than June 30 of each year. The first time the insuring organization must file the material is no later than June 30 of the calendar year that follows the year in which HCFA—

(1) Certifies a new policy; or

(2) Certifies a policy that lost certification as provided in § 403.245.

(c) If the loss ratio calculation period, used to calculate the expected loss ratio for the last actuarial certification submitted to HCFA, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with HCFA no later then the last day of that rate calculation period.

§ 403.245 Loss of certification.

(a) A policy loses certification if—

(1) The insuring organization withdraws the policy from the voluntary certification program; or

(2) HCFA determines that—

(i) The policy fails to meet the requirements specified in § 403.232(a); or

(ii) The insuring organization has failed to meet the requirements for submittal of material specified in § 403.239.

(b) If a policy loses its certification, HCFA will inform all State Commissioners and Superintendents of Insurance of that fact.

(c) If a policy that displays the emblem, or that has been marketed as a certified policy without the emblem, loses certification, the insuring organization must notify each holder of the policy, or of a certificate issued under the policy, of that fact. The notice must be in writing and sent by the earlier of—

(1) The date of the first regular premium notice after the date the policy loses its certification; or

(2) 60 days after the date the policy loses its certification.

§ 403.248 Administrative review of HCFA determinations.

(a) This section provides for administrative review if HCFA determines—

(1) Not to certify a policy; or

(2) That a policy no longer meets the standards for certification.

(b) If HCFA makes a determination specified in paragraph (a) of this section, it will send a notice to the insuring organization containing the following information:

(1) That HCFA has made such a determination.

(2) The reasons for the determination.

(3) That the insuring organization has 30 days from the date of the notice to—

(i) Request, in writing, an administrative review of the HCFA determination; and

(ii) Submit additional information to HCFA for review.

(4) That, if the insuring organization requests an administrative review, HCFA will conduct the review, as provided for in paragraph (c) of this section.

(5) That, in a case involving loss of certification, the HCFA determination will go into effect 30 days from the date

of the notice, unless the insuring organization requests an administrative review. If the insuring organization requests an administrative review, the policy retains its certification until HCFA makes a final determination.

(c) If the insuring organization requests an administrative review, HCFA will conduct the review as follows:

(1) A HCFA official, not involved in the initial HCFA determination, will initiate and complete an administrative review within 90 days of the date of the notice provided for in paragraph (b) of this section.

(2) The official will consider—

(i) The original material submitted to HCFA for review, as specified in §§ 403.232(b) or 403.239(a); and

(ii) Any additional information, that the insuring organization submits to HCFA.

(3) Within 15 days after the administrative review is completed, HCFA will inform the insuring organization in writing of the final decision, with an explanation of the final decision.

(4) If the final decision is that a policy lose its certification, the loss of certification will go into effect 15 days after the date of HCFA's notice informing the insuring organization of the final decision.

Voluntary Certification Program: Loss Ratio Provisions

§ 403.250 Loss ratio calculations: General provisions.

(a) *Basic formula.*

The expected loss ratio is calculated by determing the ratio of benefits to premiums.

(b) *Calculations.*

The insuring organization must calculate loss ratios according to the provisions of §§ 403.251, 403.253, and 403.254.

§ 403.251 Loss ratio date and time frame provisions.

(a) "Initial calculation date" means the first date of the period that the insuring organization uses to calculate the policy's expected loss ratio.

(1) The initial calculation date may be before, the same as, or after the date the insuring organization sends the policy to HCFA for review, except—

(2) The initial calculation date must not be earlier than January 1 of the calendar year in which the policy is sent to HCFA.

(b) "Loss ratio calculation period" means the period beginning with the initial calculation date and ending with the last day of the period for which the insuring organization calculates the policy's scale of premiums.

(c) To calculate "present values", the insuring organization may ignore discounting (an actuarial procedure that provides for the impact of a variety of factors, such as lapse of policies) for loss ratio calculation periods not exceeding 12 months.

§ 403.253 Calculation of benefits.

(a) *General provisions.*

(1) Except as provided for in paragraph (a)(2) of this section, calculate the amount of "benefits" by—

(i) Adding the present values on the initial calculation date of—

(A) Expected incurred benefits in the loss ratio calculation period, to—

(B) The total policy reserve at the last day of the loss ratio calculation period: and

(ii) Subtracting the total policy reserve on the initial calculation date from the sum of these values.

(2) To calculate the amount of "benefits" in the case of community or pool rated individual or group policies rerated on an annual basis, calculate the expected incurred benefits in the loss ration calculation period.

(b) *Calculation of total policy reserve.*

(1) *Option for calculation.* The insuring organization must calculate "total policy reserve" according to the provisions of paragraph (b)(2) or (b)(3) of this section.

(2) *Total policy reserve: Federal provisions.*

(i) "Total policy reserve" means the sum of—

(A) Additional reserve; and

(B) The reserve for future contingent benefits.

(ii) "Additional reserve" means the amount calculated on a net level reserve basis, using appropriate values to account for lapse, mortality, morbidity, and interest, that on the valuation date represents—

(A) The present value of expected incurred benefits over the loss ratio calculation period; less—

(B) The present value of expected net premiums over the loss ratio calculation period.

(iii) "Net premium" means the level portion of the gross premium used in calculating the additional reserve. On the day the policy is issued, the present value of the series of those portions equals the present value of the expected incurred claims over the period that the gross premiums are computed to provide coverage.

(iv) "Reserve for future contingent benefits" means the amounts, not elsewhere included, that provide for the extension of benefits after insurance coverage terminates. These benefits—

(A) Are predicated on a health condition existing on the date coverage ends;

(B) Accrue after the date coverage ends; and

(C) Are payable after the valuation date.

(3) *Total policy reserve: State provisions.* "Total policy reserve" means the total policy reserve calculated according to appropriate State law or regulation.

§ 403.254 Calculation of premiums.

(a) *General provisions.*

To calculate the amount of "premiums", calculate the present value on the initial calculation date of expected earned premiums for the loss ratio calculation period.

(b) *Specific provisions.*

(1) "Earned premium" for a given period means—

(i) Written premiums for the period; plus—

(ii) The total premium reserve at the beginning of the period; less—

(iii) The total premium reserve at the end of the period.

(2) "Written premiums in a period" means—

(i) Premiums collected in that period; plus—

(ii) Premiums due and uncollected at the end of that period; less—

(iii) Premiums due and uncollected at the beginning of that period.

(3) "Total premium reserve" means the sum of—

(i) The unearned premium reserve;

(ii) The advance premium reserve; and

(iii) The reserve for rate credits.

(4) "Unearned premium reserve" means the portion of gross premiums due that provide for days of insurance coverage after the valuation date.

(5) "Advance premium reserve" means premiums received by the insuring organization that are due after the valuation date.

(6) "Reserve for rate credits" means rate credits on a group policy that—

(i) Accrue by the valuation date of the policy; and

(ii) Are paid or credited after the valuation date.

§ 403.256 Loss ratio supporting data.

(a) For purposes of requesting HCFA certification under § 403.232, the insuring organization must submit the following loss ratio data to HCFA for review:

(1) A statement of why the policy is to be considered, for purposes of the loss

ratio standards, an individual or a group policy.

(2) The earliest age at which policyholders can purchase the policy.

(3) The general marketing method and the underwriting criteria used for the selection of applicants to whom coverage is offered.

(4) What policies are to be included under the one policy form, by the dates the policies are issued.

(5) The loss ratio calculation period.

(6) The scale of premiums for the loss ratio calculation period.

(7) The expected level of earned premiums in the loss ratio calculation period.

(8) The expected level of incurred claims in the loss ratio calculation period.

(9) A description of how the following assumptions were used in calculating the loss ratio.

(i) Morbidity.

(ii) Mortality.

(iii) Lapse.

(iv) Assumed increases in the Medicare deductible.

(v) Impact of inflation on reimbursement per service.

(vi) Interest.

(vii) Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

(viii) Expected impact on morbidity by policy duration of—

(A) The process used to select insureds from among those that apply for a policy; and

(B) Pre-existing condition clauses in the policy.

(b) For purposes of requesting continued HCFA certification under § 403.239(a), the insuring organization must submit the following to HCFA:

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since HCFA last reviewed the policy.

(2) The past loss ratio experience for the policy, including the experience of all riders and endorsements issued under the policy. The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that the insuring organization calculates—

(i) For all years of issue combined; and

(ii) Separately for each calendar year since HCFA first certified the policy.

§ 403.258 Statement of actuarial opinion.

(a) For purposes of certification requests submitted under § 403.232(b) and subsequent review as specified in § 403.239(a), "statement of actuarial opinion" means a signed declaration in which a qualified actuary states that the assumptions used in calculating the expected loss ratio are appropriate and reasonable, taking into account actual policy experience, if any, and reasonable expectations.

(b) "Qualified actuary" means—

(1) A member in good standing of the American Academy of Actuaries; or

(2) A person who has otherwise demonstrated his or her actuarial competence to the satisfaction of the Commissioner or Superintendent of Insurance of the domiciliary State of the insuring organization.

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare-Hospital Insurance Program; No. 13.774, Medicare-Supplementary Medical Insurance Program)

Dated: June 17, 1982.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: June 30, 1982.

Richard S. Schweiker,

Secretary.

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Monday
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Part IV

Department of the Interior

Bureau of Land Management

Wild Free-Roaming Horse and Burro Protection, Management and Control; Amendment To Provide a Fee for Adoption

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 4700

Wild Free-Roaming Horse and Burro Protection, Management and Control; Amendment To Provide a Fee for Adoption

AGENCY: Bureau of Land Management, Interior.

ACTION: Proposed rulemaking.

SUMMARY: This proposed rulemaking would provide for the establishment of a fee for the adoption of a wild free-roaming horse or burro. This fee would be established under the authority of section 304 of the Federal Land Policy and Management Act of 1976 and is designed to recover part of the costs incurred by the United States in connection with adoption program activities.

DATE: Comments by September 24, 1982.

ADDRESS: Comments should be sent to: Director (140), Bureau of Land Management, 1800 C Street, NW., Washington, D.C. 20240.

Comments will be available for public review in Room 5555 of the above address during regular business hours (7:45 a.m. to 4:15 p.m.), Monday through Friday.

FOR FURTHER INFORMATION CONTACT: John S. Boyles, (202) 653–9215.

SUPPLEMENTARY INFORMATION: The proposed rulemaking would establish a custodial fee that would be paid in connection with the adoption of a wild free-roaming horse or burro. The fee would be established under the authority granted the Secretary of the Interior by section 304 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1734) to require payment to reimburse the United States for reasonable costs with respect to activities such as the adoption of a wild free-roaming horse or burro. The fee would be designed to recover only a portion of the costs of the adoption program (i.e., transportation, freezemarking, veterinarian services, application processing, animal feed and handling, compliance and title transfer).

While the Secretary of the Interior does not believe that all of the factors set out in section 304 of the Federal Land Policy and Management Act must be taken into consideration, the Secretary did consider these factors as follows:

(1) The Secretary determined that a fee which represented the actual cost connected with the adoption of a wild free-roaming horse or burro would unnecessarily discourage potential adopters and lead to increased cost to the United States for holding and caring for animals and for eventually destroying them, as required by law. However, the Secretary has determined that actual costs will be charged for transportation expenses since transporting the animals in bulk reduces the transportation costs to an adopter below that for transporting a single animal. Transportation is provided as a service enjoyed only by an adopter who does not choose to pick-up an animal at a holding facility near the point of capture.

(2) The monetary value of the rights or privileges sought is approximately the value of the animal itself. The payment that would be established in this proposed rulemaking is a fairly accurate reflection of the monetary value of the benefit received by the adopter of a horse or burro.

(3) A flat fee rather than a fluctuating fee was selected because of the difficulty of determining the exact cost incurred for each animal and because it was a more efficient process. The fluctuating fee is limited to transportation costs since these are more efficiently determined.

(4) It is recognized that there is a general public interest and benefit in both the removal of excess wild free-roaming horses and burros from the public lands and in their humane treatment and care. However, the adopter also receives a benefit not shared by other members of the general public. For this reason, it was decided that the adopter should provide a share of the cost of the adoption program, but that the public interest served by the adoption is an appropriate basis for charging less than actual costs.

(5) Similarly, an adopter, by providing humane care and treatment to a wild free-roaming horse or burro, is in a sense providing a public service. Again, this was determined to be an approprate reason to reduce the amount of the custodial fee below that of actual costs.

The Bureau of Land Management has the management responsibility for wild free-roaming horses and burros located on the public lands under its jurisdiction. Over the past few months the Bureau has conducted a pilot program under which a fee has been levied for the adoption of wild free-roaming horses and burros. The payment that would be established by this proposed rulemaking is based on that pilot program. The initial reaction to the fee has been acceptable and the fee program would now be made a part of the wild free-roaming horse and burro program by the promulgation of this rulemaking.

The principal author of this proposed rulemaking is John S. Boyles, Division of Wild Horses and Burros, Bureau of Land Management, assisted by the staff of the Office of Legislation and Regulatory Management, Bureau of Land Management.

It is hereby determined that this rulemaking does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (43 U.S.C. 4332(2)(C)) is required.

The Department of the Interior has determined that this document is not a major rule under Executive Order 12291 and will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

This proposed rulemaking would set a fee for the adoption of wild free-roaming horses and burros. The fee is uniform for everyone wishing to adopt a wild free-roaming horse or burro and will have no different impact on small entities than on individuals or large entities.

List of Subjects in 43 CFR Part 4700

Advisory committees, Aircraft, Intergovernmental relations, Penalties, Public lands, Range management, Wild horses and burros, Wildlife.

PART 4700—WILD FREE-ROAMING HORSE AND BURRO PROTECTION, MANAGEMENT AND CONTROL

Under the authority of the Act of December 15, 1971, as amended (16 U.S.C. 1331–1340), the Act of June 28, 1934 (43 U.S.C. 315–315r) and the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.), it is proposed to amend Part 4700, Group 4700, Subchapter D, Chapter II of Title 43 of the Code of Federal Regulations as set forth below:

1. Section 4740.4–2 is renumbered § 4740.4–3 and is amended by revising paragraph (d) to read:

§ 4740.4–3 [Amended]

* * * * *

(d) Before wild free-roaming horses or burros are transferred, the applicant shall:

(1) Pay a custodial fee of $200 for each horse and $75 for each burro, except there shall be no custodial fee for an unweaned offspring under 6 months of age accompanying its mother, plus any transportation costs incurred for the transportation of the animals to the point of pickup; and

(2) Sign a cooperative agreement that incorporates provisions for custodial maintenance, including, but not limited to, provisions for proper maintenance of the animals and protection from inhumane treatment and commercial exploitation.

2. A new § 4740.4–2 is added to read:

§ 4740.4–2 Applications.

Any qualified person, organization or government agency wishing to take custody of a wild free-roaming horse or burro shall file an application with the Denver Service Center of the Bureau of Land Management. The application shall be filed on a form approved by the Director, Bureau of Land Management, and shall be accompanied by a nonrefundable advance payment of $25. If custody of a wild free-roaming horse or burro is granted by the authorized officer, the advance payment shall be applied against the custodial fee required to be paid at the time the cooperative agreement required by § 4740.4–3 of this title is executed.

Frank A. DuBois,

Acting Assistant Secretary of the Interior.

July 2, 1982.

[FR Doc. 82–20122 Filed 7–23–82; 8:45 am]

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