the authority citations following all the sections in Part 320 are removed.

Authority: 39 U.S.C. 401, 404, 601–606; 18 U.S.C. 1693–1699.

2. A new § 320.8 is added to read as follows:

§ 320.8 Suspension for international remailing.

(a) The operation of 39 U.S.C. 601(a)(1) through (6) and § 310.2(b)(1) through (6) of this chapter is suspended on all post routes to permit the uninterrupted carriage of letters from a point within the United States to a foreign country for deposit in its domestic or international mails for delivery to an ultimate destination outside the United States.

Example (1) The letters to overseas customers of commercial firm A in Chicago are carried by Carrier B to New York where they are delivered to Carrier C for carriage to Europe. Carrier C holds the letters in its distribution center overnight, then sorts them by country of destination and merges them with letters of other firms to those countries before starting the carriage to Europe in the morning. The carriage of firm A's letters is not interrupted. The suspension for international remailing applies to the carriage by Carrier B and by Carrier C.

Example (2) The bills addressed to foreign customers of the Chicago branch office of commercial firm D are carried by Carrier E to New York where they are delivered to the accounting department of firm D's home office. The accounting department uses the information in the bills to prepare its reports of accounts receivable. The bills are then returned to Carrier E which carries them directly to Europe where they are entered into the mails of a foreign country. The carriage of the bils from Chicago to Europe is interrupted in New York by the delivery to firm D's home office. The suspension for international remailing does not apply to the carriage from Chicago to New York. It does apply to the subsequent carriage from New York to Europe.

(b) This suspension shall not permit the shipment or carriage of a letter or letters out of the mails to any foreign country for subsequent delivery to an address within the United States.

Example (1) A number of promotional letters originated by firm F in Loss Angeles are carried by Carrier G to Europe for deposit in the mails of a foreign country. Some of the letters are addressed to persons in Europe, some to persons in the United States. The suspension for international remailing does not apply to the letters addressed to persons in the United States.

(c) Violation by a shipper or carrier of the terms of this suspension is grounds for administrative revocation of the suspension as to such shipper or carrier for a period of one year in a proceeding instituted by the General Counsel in accordance with Part 959 of this chapter. The failure of a shipper or carrier to cooperate with an authorized inspection or audit conducted by the Postal Inspection Service for the purpose of determining compliance with the terms of this suspension shall be deemed to create a persumption of a violation for the purpose of this paragraph (c) and shall shift to the shipper or carrier the burden of establishing the fact of compliance. Revocation of this suspension as to a shipper or carrier shall in no way limit other actions as to such shipper or carrier to enforce the Private Express Statutes by administrative proceedings for collection of postage (see § 310.5) or by civil or criminal proceedings.

Fred Eggleston,

Assistant General Counsel, Legislative Division.

[FR Doc. 86–13565 Filed 6–16–86; 8:45 am]

BILLING CODE 7710–12–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA Action MO 2069; FRL–3032–5]

Approval and Promulgation of State Implementation Plans: Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rulemaking (PRM).

SUMMARY: In this notice, EPA is proposing to approve a draft State Implementation Plan (SIP) revision submitted by the State of Missouri. The purpose of this revision is to reduce volatile organic compound (VOC) emissions from the refueling of motor vehicles. The reduction of VOCs is necessary to reduce ozone levels in the St. Louis ozone nonattainment area. Today's notice is published to advise the public of EPA's proposed action and to request comments.

DATE: Comments must be received on or before July 17, 1986.

ADDRESSES: Comments should be sent to Deann K. Hecht, Environmental Protection Agency, Air Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101. The State submittal is available for inspection during normal business hours at the above address, and at the Missouri Department of Natural Resources, 1101 Rear Southwest Boulevard, Jefferson City, Missouri 65102.

FOR FURTHER INFORMATION CONTACT: Deann K. Hecht at (913) 236–2893 or FTS 757–2893.

SUPPLEMENTARY INFORMATION: On March 4, 1986, the State of Missouri submitted a draft revision to the Missouri SIP. The draft revision is an amendment to State rule 10 CSR 10–5.220 for the St. Louis Metropolitan Area entitled "Control of Petroleum Liquid Storage, Loading, and Transfer." Proper public hearing was held on this amendment on January 16, 1986.

This revision will require the control of VOC emissions from the refueling of motor vehicles. This is known as State II vapor recovery. Stage I vapor recovery, controlling emissions from loading gasoline into underground tanks, has been required since 1977. The intended effect is to reduce ozone levels in the St. Louis nonattainment area by reducing the emissions of the VOCs that react in the atmosphere to form ozone. The amendment is being submitted as part of the State's plan to attain the ozone standard by December 31, 1987, which is the attainment date for the St. Louis ozone nonattainment area.

EPA has reviewed the proposed revisions and found that they will effectively achieve the desired VOC reductions and are consistent with the California Stage II vapor recovery regulations which EPA used as a benchmark for evaluation. California has the best working Stage II program, and there is no federal guideline for Stage II programs; therefore, EPA used the California regulations s a basis for reviewing the Missouri regulations.

The Missouri regulation requires owners or operators of stationary gasoline tanks with a capacity of greater than 1,000 gallons to install the Stage II vapor recovery equipment. Stationary tanks used primarily for the refueling of agricultural implements or implements of husbandry are exempt from the rule.

There are currently three types of Stage II systems in the United States: the vapor balance, the hybrid, and the vacuum assist systems. The State has not specified which of the three vapor recovery systems should be installed. The individual owners and operators may choose from the three systems; however, the State has specified that only equipment certified by the Director of the Missouri Department of Natural Resources can be installed, used, or maintained. A requirement for a vapor recovery system or a modification to a system to be certified is that the system must first be certified by the State of California Air Resources Board (ARB) as having a vapor recovery or removal efficiency of at least 95 percent. The State used a 91.5 percent efficiency to determine the emission reductions in the August 1, 1985, SIP. The regulation has

also provided for the decertification of a system by the Director if the system is prone to malperformance such that the purpose or requirements of the rule is defeated.

The Missouri regulation requires operating instructions for the vapor recovery system to be posted in the gasoline dispensing areas. This will show the public how to effectively use the vapor recovery equipment to obtain a greater in-use efficiency. The operating sign is required in California and has helped in the success of their Stage II program.

The State will submit to EPA a letter of assurance that they have adequate funding and staff to implement and enforce the Stage II program, and a letter with inspection scheduling and frequency before final approval is taken on this action. The Missouri regulation has a provision for allowing the Director to tag a vapor recovery system or component "out of order" if there is a defect in the equipment. An internal list of defects is referenced in the rule and will be made readily available to all the owners and operators. When a vapor recovery system is tagged "out of order", no person shall use or permit the use of that system or component until it has been repaired, replaced, or adjusted and the Director has: 1) reinspected the system or component, 2) found it to be in good working order, and 3) removed the "out of order" notice. The Director must reinspect the system or component within 30 days from the date on which it was marked "out of order". The "out of order" procedure has worked effectively in the California program. It forces the owner or operator of a service station to properly maintain their vapor recovery system. This allows for a greater in-use efficiency.

Final compliance with the regulation is required by December 31, 1987. The State has required the owners and operators to submit to the Director by no later than October 1, 1986, the vapor recovery system specifications and general installation details. Also, notification of installation must be submitted no later than 60 days prior to installation.

EPA is soliciting public comments on this notice and on issues relevant to EPA's proposed action. Comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the address above.

The revisions are being proposed under a procedure called "parallel processing" (47 FR 27073). EPA believes the proposed regulations are approvable; however, if the proposed revisions are substantially changed, EPA will evaluate those changes and may publish a revised NPR. If no substantial changes are made, EPA will publish a Final Rulemaking Notice on the revisions. The final rulemaking action by EPA will occur only after the SIP revisions have been adopted by Missouri and submitted to EPA for incorporation into the SIP.

Proposed Action

EPA is proposing to approve the draft SIP revision described in this Notice with the understanding that the State will not make any significant changes to the final revision.

This State submission constitutes a proposed revision to the Missouri SIP. The Administrator's decision to approve or disapprove this proposed revision will be based on the comments received and on a determination of whether or not the revision meets the requirements of Sections 110 and 172 of the Clean Air Act and of 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of State Implementation Plans, and of the 1982 SIP policy (46 FR 7184, January 22, 1981).

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant economic impact on a substantial number of small entities.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of subjects in 40. CFR Part 52: Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42. U.S.C. 7401–7642.

Dated: April 8, 1986.

Morris Kay,

Regional Administrator.

[FR Doc. 86–13613 Filed 6–16–86; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 799

[OPTS–42080; FRL–3001–9]

Triethylene Glycol Monomethyl, Monoethyl, and Monobutyl Ethers; Proposed Test Rule

Correction

In FR Doc. 86–10704, beginning on page 17883, in the issue of Thursday, May 15, 1986, make the following corrections:

PART 799—[CORRECTED]

1. On page 17883, in the subject heading of this document, "Monethyl" has been corrected to read "Monoethyl".

2. On the same page, first column, in the SUMMARY, fifth line, "monomethyl" should read "monoethyl"and in the sixth line, "glycolmonobutyl ether" was misspelled.

3. On page 17892, second column, in § 795.250(e)(2), fifth line, "Wayne" should read "Wayner".

4. On the same page, third column, fifth line, "Teratology" was misspelled.

BILLING CODE 1505–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 431

[BERC–372–P]

Medicaid Program; Mandatory Second Surgical Opinion Requirements for Medicaid Recipients

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

ACTION: Proposed rule.

SUMMARY: This proposal would amend current Medicaid rules to require that each State's Medicaid plan include a program requiring second surgical opinions for certain surgical procedures. The regulations would require, at a minimum, that the State's program apply to ten common elective surgical procedures performed for the Medicaid population in each State. Federal financial participation (FFP) would be denied for these procedures if the recipient did not obtain a second opinion unless exceptions or waivers of the requirement were applicable. States with an alternative second surgical opinion program (SSOP) or existing review programs that prevent unnecessary surgery and are cost-effective would be allowed to obtain HCFA approval of their programs in lieu of meeting new requirements.

DATE: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on July 17, 1986.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC–372–P, P.O. Box 26676, Baltimore, Maryland 21207.

Please address a copy of comments on information collection requirements to:

Fay Iudicello, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208,

New Executive Office Building, Washington, DC 20503.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, D.C., or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC–372–P. Comments will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309–G of the Department's offices at 200 Independence Ave., SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202–245–7890).

FOR FURTHER INFORMATION CONTACT: Ernestine Jones, (301) 597–0321.

SUPPLEMENTARY INFORMATION:

I. Background

A. Description of Second Surgical Opinion Programs (SSOP)

Second surgical opinion programs are formal mechanisms whereby patients recommended for surgery are either encouraged or required to obtain an independent medical opinion prior to performance of the procedure. The purpose of the second opinion is to inform a patient whether an independent medical evaluation confirms the diagnosis and the necessity of surgery, and to offer for consideration any alternative treatment. Second opinion programs most effectively focus on elective surgical procedures (i.e., those that may be planned in advance with no risk to patient life or well-being).

Second opinion programs can be either voluntary or mandatory. In a voluntary program, the second opinion is available as a health insurance benefit for use at the patient's discretion. In a mandatory program, the third party insurer requires the patient to obtain a second opinion prior to surgery as a condition of reimbursement. That is, payment may be denied for the surgery unless a second opinion has been obtained.

In both voluntary and mandatory second opinion programs, the final decision to have surgery is generally made by the patient. Since the focus of the program is on increased patient awareness of both surgical and nonsurgical treatment options, most insurers do not require the second opinion to endorse the surgery option as a condition for payment for the surgery.

Although there can be great variation of second surgical opinion programs, there are a number of elements common to all. These are: (a) Notification to patients and the medical community of the availability and requirements of the second opinion; (b) identification of surgical procedures for which the second opinion is required or suggested; (c) identification of physicians who are available and qualified to provide second opinions; (d) provision for payment for the independent second opinion; and (e) a referral mechanism for patients and/or medical records. Mandatory programs usually also include a pre-screening aspect to identify potential recipients of unnecessary surgery, a listing of exceptions to the screening requirement based on geographical or time constraints, or other considerations; and a mechanism to verify that a second opinion was obtained prior to the surgery.

B. SSOPs Under Medicaid

Between 1971 and 1980, the incidence of surgical procedures increased at a rate more than four times greater than that of the population. In January 1976, the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce reported that an estimated 2.4 million unnecessary surgeries were performed in 1974 at the expense of 11,900 lives and about $4 billion. The Subcommittee recommended that the then Department of Health, Education and Welfare promptly institute a program of independent second professional opinions to confirm the need for elective surgery underwritten by Medicare and Medicaid.

In an effort to comply with Congress, mandate, we initiated a voluntary National Second Surgical Opinion Program (NSSOP) for Medicare and Medicaid in 1977, which is ongoing. This program encourages patients to be more informed and involved in decisions on their health through the use of public service announcements, referral centers, and patient information and educational materials on the advantage of second opinions. In addition, we initiated several second opinion demonstrations.

Forty-two State Medicaid programs offer some type of SSOP, the majority of which are voluntary. These programs encourage individuals to obtain second opinions at no cost to themselves, but do not require the individual to participate, nor to avoid surgery if the second opinion suggests alternative treatment.

Currently, there are 10 States that have adopted a mandatory SSOP for their cost containment initiative. These States focus their SSOPs on up to ten elective surgical procedures that, in their experience, are frequently performed for the Medicaid population. In these States, Medicaid does not reimburse the physicians for performing the surgery without a second opinion. These States are Massachusetts, Michigan, Minnesota, Missouri, New Jersey, Oregon, Tennessee, Virginia, Wisconsin, and Washington. The State of New York is in the process of establishing a mandatory second opinion requirement in its Medicaid program.

C. Effectiveness of SSOPs

In March 1982, the Secretary submitted a report to Congress based on the results of our evaluation of second surgical opinion programs. The finding revealed that mandatory programs have proven successful for Medicaid and have the potential for substantial cost savings. The mandated SSOPs operated by State Medicaid Agencies clearly demonstrated that they were effective in reducing both the volume of elective surgeries and the costs associated with them. Three States, Massachusetts, Michigan, and Wisconsin had performed cost studies and all concluded that the SSOPs will result in a 20 to 35 percent reduction in elective surgeries at annual cost savings of from $1 million to $3.7 million, an average of $3.48 for each Medicaid recipient residing in these States.

II. Proposed Mandatory Second Surgical Opinion Program

Section 1902(a)(30)(A) of the Social Security Act provides that a State plan for medical assistance must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services to assure that payments are consistent with efficiency, economy, and quality of care." Under this authority and section 1902(a)(4) of the Act which provides that State plans shall include "methods of administration found by the Secretary to be necessary for proper and efficient operation of the plan", some States now implement voluntary or mandatory second surgical opinion programs. We believe the clear evidence of program savings and patient well-being resulting from madatory SSOPs make it appropriate to require all States to use mandatory SSOPs or effective

alternatives to assure efficient program administration.

We propose to require that each State's Medicaid plan include a madatory program for a second surgical opinion for selected elective high-cost procedures which generally can be postponed without undue risk to the patient. The objectives of the mandatory program are to prevent unnecessary surgery and be cost-effective. State plans would be required to provide that payment would not be made if the recipient did not obtain a second opinion (unless stated exceptions were applicable). Federal financial participation (FFP) for the identified procedures would not be available if the recipient did not obtain a second opinion under such circumstances.

Second surgical opinions would be required whether the elective surgical procedures were performed on an inpatient or outpatient basis. Federal financial participation would be available for the second opinion itself even if it does not concur with the initial recommendation for surgery. If the second opinion does not confirm the first, a State, at its option, may obtain Federal financial participation for a third opinion to corroborate need for surgery.

In recognition of variations in utilization of surgical procedures in different States, and variations in physician referral patterns, we are providing States considerable latitude in designing their mandatory SSOP. For example, when the second opinion does not confirm the first, the State, at its option, may refer the recipient for a third opinion or may decide to allow the surgery if the recipient still requests it. Another State option would be to deny payment for the surgery under § 1902(a)(30)(A) of the Act, which allows States to exclude services determined unnecessary. Regardless of specific variations, State programs must comply with certain minimum requirements, as identified below.

We would require, at a minimum, that the State's program apply to ten elective surgical procedures that are costly or frequently performed for the Medicaid population in the State. We would define surgery as a procedure which can be scheduled in advance, i.e., not an emergency procedure, and one that is discretionary on the part of both physician and patient. If surgery is "elective", failure to undergo such surgery does not pose a mortality threat to the patient and scientific evidence does not indicate clearly greater life expectancy as a result of election of the surgery.

The State plan would have to name the procedures and specify the criteria used to select them. We would expect the criteria to take into account the costs of the procedure and attendant services (e.g., hospitalization and follow-up care), anticipated high non-confirmation rates, volume of procedures and the elective nature of the procedure. Procedures identified in Massachusetts, the first State to use a mandatory SSOP in its Medicaid program have included, for example, tonsillectomy/adenoidectomy, menisectomy, hysterectomy, cholecystemy, submucous resection, spinal fusion/disc surgery, hemorrhoidectomy and excision of varicose veins.

The State agency must analyze SSOP data, including cost data, at least annually to determine whether changes should be made in the list of elective surgical procedures. The State must agree to provide such information upon request to the Department.

The State would be required to establish a mechanism for obtaining the second opinon from a qualified physician, and would be granted flexibility in determining physicians' qualifications for issuing second opinions. For example, a State may choose to restrict opinions for some procedures to certain specialists or it may identify certain physicians as a group to be available for any second opinion patient referrals. Further, a State would be free to contract with entities that currently perform review functions to provide physicians for second opinion referrals. Regardless of the mechanism established by the State, the agency must specify the qualifications of those physicians who would be consulted, and must assure that the second opinion is not furnished by a physician whose evaluation cannot be considered "independent" due to common interest or other close ties with the first opinion physician.

All second opinion programs are based on medical judgments and we recognize that many elements enter into a medical decision to recommend one or another form of treatment. The second opinion must consider the proposed surgery as one option and then make a recommendation as to preferred mode of treatment based on medical findings.

Second opinions would not be required under certain circumstances. If it were necessary for a surgical procedure listed by the State to be performed as an emergency, the need for a second opinion requirement would be waived. Similarly, if a State agency develops criteria for screening cases to determine whether second surgical opinions are necessary (e.g., diagnostic evidence of the patient's condition is such that approval may be given without the need for a second opinion), it may waive the requirement for cases which meet the criteria. This provision is intended to permit States to avoid unnecessary expenses in connection with the SSOP in cases where a screening process proves effective, as it has done in some existing programs. In addition, should the State determine that there is no qualified physician available to furnish a second opinion due to distance or specialty considerations, the requirement would be waived. The State would be free to establish areas where distance precludes obtaining a second opinion. In most instances we would not expect a Medicaid recipient to be required to travel more than the distance that the individual would normally be required to travel to receive medical services in his or her geographical area. Finally, Medicaid recipients enrolled in an HMO or competitive medical plan (CMP) having a risk-sharing contract under Medicaid would be exempt from the second opinion requirement because HMOs and CMPs generally reimbursed on a risk basis use other approaches which achieve the same results as a second opinion program. Any action resulting from the application of the State's review system which results in the denial of Medicaid payment, either prospectively or retrospectively, is subject to the usual hearings and appeal rights as cited under 42 CFR Part 431 Subpart E.

State programs would be required to notify all recipients and physicians, hospitals and ambulatory surgical facilities participating in the Medicaid program of the SSOP and its requirements, including the applicable list of surgical procedures to which such requirements apply, and furnish information about the mechanism for referring recipients for second opinions.

States that are currently operating review programs which HCFA determines achieve the objectives of cost effectiveness and preventing unnecessary surgery, as stated in these regulations, will not be required to follow the procedures in these regulations. For example, some States may achieve these objectives through their claims review process, or by reviewing on a prepayment basis requests for all or certain elective procedures. To the extent that the State's procedures achieve the objectives of these regulations, they may be exempt from these requirements.

States may submit a description of their review systems to HCFA for a determination as to whether they achieve the objectives of this regulation. Overall, HCFA's approval of an alternative program will be based on its evaluation as to whether the program is, at a minimum, equal to the outcomes to be achieved in an SSOP, based on the objectives set forth in these regulations. If HCFA determines that the existing system fails to meet the SSOP objectives, States will be given the option of either upgrading existing programs, or implementing an SSOP, if such an upgrading will meet the objectives of the regulations. Existing programs would have 90 days after the effective date of this regulation to come into compliance. Similarly, States not currently operating SSOP programs may substitute an alternative approach if HCFA finds that the proposed system will accomplish the same objectives.

HCFA may withdraw its approval of the alternative to a mandatory SSOP if it finds that the system is not satisfactorily accomplishing those purposes. In such cases, the State must institute this an SSOP within 90 days from the date the alternative plan was disapproved by HCFA.

In accordance with the President's budget for fiscal year 1987, we propose this regulation be effective October 1, 1986, but States would have 90 days after the effective date of publication of the final rule to come fully into compliance. This will allow States sufficient time to establish the mandatory second surgical opinion program, to upgrade an existing program, or to seek approval of an alternative plan or review program, and to advise all affected parties.

III. Provisions of the Proposed Regulations

We propose to add a new Subpart G to Part 431 of Title 42. This regulation, as mentioned above, would impose a Federal requirement that each State's Medicaid plan include a program for mandatory second surgical opinions for certain procedures.

Section 431.400 would be added to include the basis and scope for a mandatory second surgical opinion program and necessary definitions.

Section 431.401 would specify that the State plan must include the requirements of this subpart, or the State must include an approved alternative program.

Section 431.402 would require that the State's program apply to a selected list of ten, or more at State option, elective surgical procedures as outlined in the regulation text. The second opinion must, at a minimum, address the medical appropriateness of the proposed surgery. Federal financial participation (FFP) would be denied for elective surgical procedures specified by the State if the recipient did not obtain a second opinion (unless exceptions or waivers of the requirement were applicable).

Section 431.403 would outline the procedures for selecting elective surgeries for inclusion in the SSOP.

In § 431.404 we would specify the criteria for a State agency to consider when establishing procedures for SSOPs.

Section 431.405 would require that an agency notify all Medicaid recipients of the requirements of the Second Surgical Opinion program.

Section 431.406 would require that an agency notify all physicians, hospitals and facilities participating in the Medicaid program which provide services subject to the second opinion reequirements.

IV. Regulatory Impact Statement and Regulatory Flexibility Analysis

A. Introduction

Executive Order 12291 (E.O. 12291) requires us to prepare and publish an initial regulatory impact analysis for any proposed regulations that are likely to meet criteria for a "major rule". A major rule is one that would result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or any geographical regions; or

(3) 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.

In addition, consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare and publish an initial regulatory flexibility analysis for proposed regulations unless the Secretary certifies that the regulations would not have a significant impact on a substantial number of small entities. States are not included in the definition of small entity under the RFA. In addition, since they are individuals, Medicaid recipients are not considered small entities under the RFA. However, hospitals, ambulatory surgical centers and physicians, which would be affected by this proposed rule, are considered small entities.

This proposed rule would not meet the criteria for a major rule under E.O. 12291. Although we do not expect many physicians, hospitals, or ambulatory surgical centers would experience substantial loss of revenue as a result of a mandatory SSOP, the changes in behavior associated with the "sentinel effect", the required provision of information to patients and making referrals for second opinions, may be considered significant. Therefore, we have prepared a voluntary regulatory flexibility analysis.

B. Estimated Program Savings

Based on the data currently available to us, this regulation is expected to save between $20 and $70 million annually in Medicaid program expenditures for Federal and State governments, combined, by making it mandatory to require second surgical opinions for selected elective surgical procedures.

ESTIMATED ANNUAL SAVINGS OF MEDICAID MANDATORY SSOP (MEDICAL ASSISTANT PAYMENT)

[Rounded to nearest $5 million]

Federal	$10 to $40 million.
State	$10 to $30 million.
Total	$20 to $70 million.

The wide range of potential savings is related to the options available to States. Our estimate of savings is based on the difference between the cost of surgery and the combined cost of a second physician consultation and any alternative treatment that may be required, and takes into account that there would be additional program costs associated with obtaining second opinions. However, some aspects of costs and savings were too difficult to quantify. For example, some savings would be associated with the avoidance of the costs of ancillary services associated with surgical procedures not performed, and some offsetting costs could result from alternative treatment furnished instead of surgery. First year savings would be somewhat less than eventual full annual savings because of the delays necessary for States to amend their State plans and implement programs, and lags in reimbursement claims. In addition, program savings would be offset by administrative costs

for the States, of which the Federal Government would bear a share.

C. Discussion

There are currrently ten States with mandatory second surgical opinion programs. Three States have reported $1 million in savings annually as a result of their mandatory programs. The surgery rates have declined in these States attributable both to a direct effect on patients referred to the SSOP and to a "sentinel effect"; that is, that physicians recommended fewer surgeries.

Physician behavior could be affected in several ways by this proposed rule. The physicians who recommend and perform surgical procedures may prescribe surgery less frequently. To the extent that surgeons perform fewer surgeries as a preferred form of treatment, whether as a result of this "sentinel" effect, or as a result of patient election to avoid surgery, physician income could be reduced. However, there would be an increase in the number of referrals and consultations as a result of this proposed rule. The cost of these physicians' services would, to some extent, offset savings attributable to reduced surgical costs, and in the case of individual physicians who provide second or third opinions, also might offset in part any income reduction attributable to a reduction in the number of surgeries performed. Certain physicians might experience an increased consultation workload, with a concomitant increase in income, when they agree to participate in the State programs.

Physicians and facilities would have to assure that each recipient was informed of the need for a second opinion and obtained it in order to have the procedure ultimately paid for by the Medicaid program. This could place additional administrative burdens on the physician, the facility at which surgery would occur, and the State Medicaid agency, to ensure that preparation of a second opinion was confirmed prior to performance of surgery.

Hospitals and ambulatory surgical centers could be affected by lesser volumes of elective surgery. Delays in admissions could occur because the patients would be involved in setting up appointments for second or third opinions.

We expect this proposal would enhance quality of services among health care providers and practitioners by avoiding unnecessary surgery. Further, since surgery is relatively resource-intensive compared to alternative treatment modalities, avoidance of unnecessary surgery would be expected to improve overall system productivity, since some resources would presumably be redistributed more effectively.

The SSOP would benefit Medicaid recipients by giving them a more active part in the decision of whether to undergo surgery that might not be in their best interest. Costsharing requirements would be waived for the second or third opinion or for related diagnostic services. Further, Medicaid recipients would be better informed and more aware of alternatives to surgery. As a consequence of obtaining a second opinion, the elective procedures performed would be based on informed decisions by recipients more aware of the surgery to be performed and alternative treatment to replace the surgery.

If a recipient were to elect not to get a second opinion, or if coverage were denied under a State utilization control program as a result of a negative second opinion, his or her costs for subsequent surgery could increase because the burden of paying for the resulting surgery and attendant services would not be borne by the Medicaid program. This could also increase costs for the physician and provider if the recipient were unable to pay for the surgery. However, we expect recipients would rarely choose surgery without obtaining a second opinion, since, in the case of a recipient electing to have surgery, the financial interests of recipient, physician, and provider would all be served by obtaining the second opinion.

V. Reporting and Recordkeeping Requirements

Sections 431.401, 431.404 (a), (b), (c), (e), and (g), 431.405 and 431.406 of this proposed rule contain information collection requirements that are subject to the Office of Management and Budget review under the Paperwork Reduction Act of 1980. A notice will be published in the **Federal Register** when approval is obtained. Other organizations and individuals desiring to submit comments on the information and collection requirements should follow the directions in the ADDRESS section of this preamble.

VI. Response to Comments

Because of the large number of comments we receive, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments and will respond to the issues in the preamble to that rule.

List of Subjects in 42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 431 would be amended as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The table of contents is amended by adding a new Subpart G to Part 431 and reserving Subpart H–L to read as follows:

Subpart G—Mandatory Second Surgical Opinion Program Under Medicaid

Sec.
431.400 Basis, scope and definitions.
431.401 State plan requirements.
431.402 Application of second surgical opinions.
431.403 Covered elective surgical procedures.
431.404 Procedures for SSOPs.
431.405 Notfication to recipients.
431.406 Notification to physicians, hospitals and ambulatory surgical facilities.

Subparts H–L—[Reserved]

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

2. A new Subpart G is added to read as follows:

Subpart G—Mandatory Second Surgical Opinion Program Under Medicaid

§ 431.400 Basis, scope and definitions.

(a) *Basis.* This subpart is based on section 1902(a)(30)(A) of the Act which requires that State plans contain safeguards against unnecessary utilization of care and services and assure that payments are consistent with efficency, economy and quality of care. This subpart is also based on section 1902(a)(4) of the Act which provides that States plans shall include administrative methods necessary for proper and efficient operations of the plan.

(b) *Scope.* This subpart establishes general requirements for a mandatory second surgical opinion program (SSOP) or approved alternative program under Medicaid for each State as a State plan requirement. The objectives of the SSOP are to prevent unnecessary surgery and be cost-effective. State plans must provide that unless certain exceptions apply, a recipient must obtain an independent evaluation of the need for surgery for specified elective surgeries prior to their performance, as a condition for Medicaid payment.

(c) *Definitions.* As used in this part: "Elective surgery" means a surgical procedure which can be scheduled in

advance, (i.e., not an emergency procedure), and one which is discretionary on the part of both physician and patient. Failure to undergo elective surgery does not pose a mortality threat to the patient, and scientific evidence does not indicate clearly greater life expectancy if the surgery is elected.

"Emergency surgery" is characterized by urgent need for performance; is surgery performed for conditions and circumstances which afford no choice of alternatives either to the physician or to the recipient as to performance or non-performance; or is surgery which if delayed, could reasonably result in death or permanent impairment of health.

"First opinion" means the medical judgment by a physician qualified to evaluate the patient's condition that the procedure is medically appropriate.

"Review program" means a systematic plan for utilization review to determine whether a second surgical opinion should be obtained for selected elective surgical procedures furnished to Medicaid recipients. The plan must provide for review of each case for elective surgical procedures which applies to inpatient services of a hospital or outpatient services.

"Second opinion" means an additional surgical or medical evaluation of a recommendation for elective surgery given by a physician in active practice qualified to evaluate the patient's condition.

"Second surgical opinion program (SSOP)" means a State program under which Medicaid recipients may be required to obtain an additional physician consultation as a condition of Medicaid payment for the surgery and related services.

§ 1431.401 State plan requirements.

(a) A State plan must include the requirements of §§ 431.402 through 431.406, or the State must have in place a system for reviewing the need for surgical procedures which HCFA determines achieves the objectives of these provisions.

(b) A State plan must specify implementing details concerning the SSOP, consistent with requirements of this subpart.

§ 1431.402 Application of second surgical opinions.

(a) *General rule.* Federal financial participation (FFP) is not available for those elective surgical procedures specified by the State if the recipient did not obtain a second opinion, unless exceptions or waivers of the requirement were applicable as stated in paragraph (b) of this section. For those elective surgical procedures specified by the State in accordance with § 431.403 of this subpart, but in no case fewer than ten such procedures, a second surgical opinion must—

(1) Be obtained from a physician that meets the qualifications of § 431.404; and

(2) Address the medical appropriateness of the proposed surgery as the preferred mode of treatment.

(b) *Exceptions.* The recipient is not required to obtain a second surgical opinion with respect to procedures subject to paragraph (a) of this section if—

(1) The State's procedures provide for screening of proposed surgical procedures to determine whether the diagnostic evidence of the patient's condition is such that approval may be given without the need for a second opinion;

(2) The recipient is enrolled in a HMO or prepaid health plan having a risk-sharing contract with the State Medicaid agency;

(3) The procedure, although generally elective, is being performed as an emergency procedure as defined in § 431.400;

(4) The State agency determines there is no qualified physician available to give a second opinion due to considerations of distance or physician specialty.

§ 1431.403 Covered elective surgical procedures.

In selecting elective procedures for inclusion in its SSOP, the State agency must consider both outpatient and inpatient procedures and determine whether the procedure—

(a) Is one that can generally be postponed without creating an undue risk to the recipient;

(b) Is costly or is frequently performed for Medicaid recipients; and

(c) Is among those found to be of questionable medical necessity based upon reputable data or medical literature available to the State agency.

§ 431.404 Procedures for SSOPs.

(a) The State agency must establish procedures under which recipients are required to obtain a second surgical opinion prior to undergoing surgery for certain elective surgery. A State may, at its option, also provide for obtaining a third opinion to confirm either the initial or second opinion.

(b) The agency must provide information and assistance to the recipients which would include, as a minimum.—

(1) A list of physicians determined by the State agency to be qualified to provide second opinions and who have agreed to do so or other direct referral mechanism established by the agency for this purpose; and

(2) Information about how to retrieve pertinent medical records from the physician who provided the first opinion (or, if necessary, from the hospital or surgical facility) and make available the necessary information to the physician being asked to provide the second opinion or other State established mechanism for this purpose.

(c) The State agency must analyze SSOP data (including cost data) and update, if necessary, the list of elective procedures at least once a year. The State must agree to provide such information to the Secretary of his designee upon request.

(d) The State agency may not impose a cost sharing requirement on a recipient for such a second (or, at State option where the two opinions disagree, a third) opinion, nor for necessary diagnostic services covered under the State plan which are required for preparation of the second or third opinion.

(e) The State agency must designate, for each surgical procedure on the list for which a second opinion is required, those specialties and qualifications of those physicians who would be consulted for a second opinion. The State agency requirements must assure that no conflict of interest exists between the first opinion physician and physicians providing a second or third opinion.

(f) A State must have its SSOP implemented within 90 days after the effective date of this regulation.

(g) A State with an alternative SSOP plan or an existing review program that prevents unnecessary surgery and is cost effective must obtain HCFA's approval of its program. The agency must submit the appropriate information to make this determination to HCFA within 30 days of the effective date of this regulation.

(h) A State with an alternative SSOP plan that does not meet HCFA's approval or with an existing review program that does not meet HCFA's approval must upgrade its system to meet HCFA's approval or implement these SSOP requirements within 90 days from the date the alternative plan or review program was disapproved.

§ 431.405 Notification to recipients.

The State agency must notify all recipients of the SSOP and its requirements, including the applicable

list of surgical procedures to which such requirements apply, exceptions, and general information about the referral services.

§ 431.406 Notification to physicians, hospitals and ambulatory surgical facilities.

The State agency must notify all physicians, hospitals and ambulatory surgical facilities which provide services subject to the SSOP and are participating in the Medicaid program of the requirements of the SSOP. The notice must also include the applicable list of surgical procedures to which the requirements apply.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance)

Dated: May 19, 1986.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: May 27, 1986.

Otis R. Bowen,

Secretary.

[FR Doc. 86-13666 Filed 6-16-86; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 192

[Docket No. PS-91; Notice 1]

Interval for Review and Calculation of Relief Device Capacity

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to permit calculations made to verify capacity of relieving devices to be performed on the same interval (not to exceed 15 months, but at least once each calendar year) as required if capacity tests are actually performed. The present interval, "one-year," causes inconvenience in scheduling and possibly added inspection costs with no greater safety benefits than the interval proposed here.

DATE: Interested persons are invited to submit written comments on this proposal by August 18, 1986. Late filed comments will be considered to the extent practicable.

ADDRESS: Comments should identify the docket and notice numbers and be submitted in triplicate to the Dockets Branch, Room 8426, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 426-3148. All comments and other docket material are available in Room 8426 for inspection and copying between the hours of 8:30 a.m. and 5:00 p.m. each working day.

FOR FURTHER INFORMATION CONTACT: Paul J. Cory, (202) 426-2082. Copies of the proposal and documents related thereto may be obtained from the Dockets Branch, (202) 426-3148.

SUPPLEMENTARY INFORMATION:

Background

The inspections and tests required by §§ 192.739 and 192.743(a) of relieving devices as well as other equipment must be conducted "at intervals not to exceed 15 months, but at least once each calendar year." The inspections and tests are to determine that the equipment is in good mechanical condition, has adequate capacity, is reliable, has a correct set pressure and is properly installed and protected. A companion rule, § 192.743(b), permits operators to substitute "review and calculation of required capacity" when an actual test of capacity is not feasible. This review and calculation must be made "at intervals not exceeding one-year."

The difference between the inspection and test interval in §§ 192.739 and 192.743(a) and the "one year" period under § 192.743(b) if forcing pipeline operators to set different schedules for the inspections and tests of relieving devices versus review and calculation, which may increase costs and is inconvenient. Further, although actual testing is preferred, the objective of each of these rules, assuring adequate capacity, is the same. There is no safety justification for requiring the calculation of capacity under § 192.743(b) on a schedule that is different, not necessarily more frequent, than the schedule for tests and inspections under §§ 192.739 and 192.743(a).

On November 18, 1985, the Gas Piping Technology Committee of the American Society of Mechanical Engineers petitioned RSPA to amend § 192.743(b) to permit the review and calculation of relieving device capacity to be made at the same interval permitted for the testing of relieving devices under § 192.743(a). (Petition No. P-31).

In view of the undue burden and potentially added costs of scheduling the tests and inspections of relieving devices under §§ 192.739 and 192.743(a) on a different basis from the alternative review and calculation under § 192.743(b), RSPA is proposing to amend § 192.743(b) to permit the review and calculation to be made "at intervals not to exceed 15 months, but at least once each calendar year."

It should be noted that under the existing and proposed versions § 192.743(b), calculation of capacity need not be repeated if the review documents that the parameters used in the previous calculation have not changed to make existing capacity inadequate.

Classification

Since this proposed rule will have a positive effect on the economy of less that $100 million a year, will result in cost savings to consumers, industry, and government agencies, and no adverse impacts are anticipated the proposed rule is not "major" under Executive Order 12991. Also, it is not "significant" under Department of Transportation procedures (44 FR 11034). RSPA believes that the proposed rule will reduce the costs and inconvenience of scheduling the inspections and tests of relief values under § 192.43. However, this savings is not expected to be large enough to warrant preparation of a Draft Regulatory Evaluation.

Based on the facts available concerning the imapct of this rulemaking action, I certify pursuant to section 605 of the Regulatory Flexibility Act that the action will not, if adopted as final, have a significant economic impact on a substantial number of small entities.

List of Subjects in 49 CFR Part 192

Pipeline safety, Relieving devises, Inspections, Testing.

PART 192—[AMENDED]

In view of the above, RSPA, proposes to amend Part 192 ot Title 49 of the Code of Federal Regulations as follows:

1. The authority citation for Part 192 continues to read as set forth below:

Authority: 49 U.S.C. 1672; U.S.C. 1804; 49 CFR 1.53 and Appendix A of Part L.

2. Section 192.743(b) would be revised to read as follows:

§ 192.743 Pressure limiting and regulating stations: Testing of relief devices.

* * * * *

(b) If a test is not feasible, review and calculation of the required capacity of the relieving device at each station must be made, at intervals not exceeding 15 months, but at least once each calendar year, and these required capacities compared with the rated or experimentally determined relieving capacity of the device for the operating conditions under which it works.

* * * * *

Issued in Washington, DC, on June 12, 1986, under authority delegated by CFR Part 106, Appendix A.

Robert L. Paullin,

Director, Office of Pipeline Safety.

[FR Doc. 86-13670 Filed 6-16-86; 8:45 am]

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