

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 414**

[CMS-1223-IFC]

RIN 0938-AL99

Medicare Program; Criteria for Submitting Supplemental Practice Expense Survey Data Under the Physician Fee Schedule**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Interim final rule with comment period.

SUMMARY: This interim final rule revises criteria that we apply to supplemental survey information supplied by physician, non-physician, and supplier groups for use in determining practice expense relative value units under the physician fee schedule. This interim final rule solicits public comments on the revised criteria for supplemental surveys.

DATES: *Effective date:* This regulation is effective upon publication.

Comment date: We will consider comments concerning criteria for supplemental surveys if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 27, 2002.

ADDRESSES: In commenting, please refer to file code CMS-1223-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1223-IFC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are

encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Stephanie Monroe, (410) 786-6864.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. Please call (410) 786-7197 to schedule an appointment to view the public comments.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 (or toll-free at 1-888-293-6498) or by faxing to (202) 512-2250. The cost for each copy is \$9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background*A. Legislative History*

Section 212 of the Balanced Budget Refinement Act of 1999 (BBRA) requires us to establish a process under which we will accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations

to supplement the data we normally collect in determining the practice expense component of the physician fee schedule. Section 212(b) states that the process must be available for payments for the 2001 and 2002 physician fee schedules. In the May 3, 2000 interim final rule with comment period (65 FR 25664), we established the criteria under which we would accept supplemental data in calendar year (CY) 2000 for use in computing practice expense relative value units (RVUs) for CY 2001. Among other criteria, we indicated a precision level that the supplemental data would have to meet to be accepted. We revised the precision criteria in the November 1, 2000 final rule (65 FR 65383) for data received in 2001. In the November 1, 2001 final rule (66 FR 55254), we extended the deadline for receipt of supplemental data for an additional 2 years.

B. Current Criteria for Acceptance of Supplemental Data

We established criteria that apply to supplemental surveys in the May 3, 2000 interim final rule with comment period (65 FR 26664). Any CMS-designated specialty group may submit supplemental survey data. (Please see the May 3, 2000 interim final rule (65 FR 25665) for the list of designated specialties). In addition, the following are the specific criteria we will use:

- Physician groups must draw their sample from the American Medical Association (AMA) Physician Masterfile to ensure a nationally representative sample that includes both members and non-members of a physician specialty group. Physician groups must arrange for the AMA to send the sample directly to their survey contractor to ensure confidentiality of the sample; that is, to ensure comparability in the methods and data collected, specialties must not know the names of the specific individuals in the sample.

- Non-physician specialties not included in the AMA's Socioeconomic Monitoring System (SMS) must develop a method to draw a nationally representative sample of members and non-members. At a minimum, these groups must include former members in their survey sample. The sample must be drawn by the non-physician group's survey contractor, or another independent party, in a way that ensures the confidentiality of the sample; that is, to ensure comparability in the methods and data collected, specialties must not know the names of the specific individuals in the sample.

- A group (or its contractors) must conduct the survey based on the SMS survey instruments and protocols,

including administration and follow-up efforts and definitions of practice expense and hours in patient care. In addition, any cover letters or other information furnished to survey sample participants must be comparable to the information previously supplied by the SMS contractor to its sample participants.

- Physician groups must use a contractor that has experience with the SMS or a survey firm with experience successfully conducting national multi-specialty surveys of physicians using nationally representative random samples.

- Physician groups or their contractors must submit raw survey data to us, including all complete and incomplete survey responses as well as any cover letters and instructions that accompanied the survey, by August 1, 2002 for data analysis and editing to ensure consistency. All personal identifiers in the raw data must be eliminated.

- The physician practice expense data from surveys that we use in our code-level practice expense calculations are the practice expenses per physician hour in the six practice expense categories—clinical labor, medical supplies, medical equipment, administrative labor, office overhead, and other. Supplemental survey data must include data for these categories.

In addition to the above survey criteria, we indicated that we would review the precision of the survey. Based on our review of existing physician practice expense surveys, we indicated that the ratio of the standard error of the mean to the mean expressed as a percent, should not be greater than 10 percent for overall practice expenses or practice expenses per hour. We modified this criterion in the physician fee schedule final rule published on November 1, 2000 to require a 90-percent confidence interval with a range of plus or minus 10 percent of the mean (that is, 1.645 times the standard error of the mean, divided by the mean, should be equal to or less than 10 percent of the mean.)

Since the physician fee schedule is a national fee schedule, the survey must be representative of the target population nationwide. We can presume national representativeness if a random sample is drawn from a complete nationwide listing of the physician specialty, subspecialty, or supplier category and the response rate, that this, the percent of usable responses received from the sample, is high. If any of these conditions (random sample, complete nationwide listing, and high response rate) are not achieved, then the

potential impacts of the deviations upon national representativeness must be explored and documented. For example, if the response rate is low, then justification must be furnished to demonstrate that the responders are not significantly different from non-responders with regard to factors affecting practice expense. Differential weighting of subsamples may improve the representativeness. Minor deviations from national representativeness may be acceptable.

We believe that it is impossible and impractical to set rigid cutoffs for most of these criteria, especially for national representativeness. We are attempting to be as flexible as possible consistent with our goal of obtaining new surveys of practice expense data that are scientifically sound and methodologically consistent with our existing estimates. For instance, a specialty may include different types of physician practices (for example, urban versus rural, academic versus non-academic, interventional versus non-interventional) that exhibit different patterns of practice expense. Similarly, a stratified sampling of these different types of practices may be a more efficient sampling strategy than a simple random sample of the entire specialty. We welcome surveys with more sophisticated designs and these types of survey variations if relevance to our criteria is documented.

We would need to make the supplemental survey data that we determine complies with the above criteria consistent with the SMS data we are using. Specifically, we are currently using 1994 through 1996 specialty practice expense per-hour data from the SMS. Thus, we would deflate supplemental survey data to be consistent with the timeframe of the data from other specialties from the SMS. For example, since the midpoint of the SMS data we currently use is 1995, we would deflate supplemental survey data to 1995 using the Medicare Economic Index. Therefore, any comparison between supplemental survey information and the SMS practice expense per-hour data we are currently using should take into account that the data should be deflated to 1995 costs. We will make comparable adjustments to bring future supplemental surveys into the same timeframe as SMS data used in the future.

In addition, if a specialty is represented in the SMS data, we will weight-average (based on the number of survey responses) the supplemental data with the existing SMS data already being used. If the specialty is not

represented in the SMS data, we will substitute the new data for the crosswalked SMS data currently being used for the specialty. Specialties may also wish to consider that, under our methodology for determining practice expenses, we calculate specialty-specific practice expense RVUs based on estimates of practice expenses for specific procedures in combination with the SMS data. The specialty-specific practice expense RVUs are weight-averaged based on the frequency of allowed services performed by a given specialty. Thus, supplemental data from a specialty that represents a small proportion of the allowed services for a given procedure code will have little influence on the procedure's final value in the weighted averaging.

II. Provisions of the Interim Final Rule

In this interim final rule with comment, we are revising the precision criteria that a survey must meet to be accepted. Further, we are amending § 414.22(b)(6) to reflect the 2-year extension in the deadline for submitting supplemental data. We will accept supplemental data that meet the established criteria that we receive by August 1, 2002 to determine CY 2003 practice expense RVUs and by August 1, 2003 to determine CY 2004 practice expense RVUs.

We have reviewed the criteria set forth in the November 1, 2000 final rule for the acceptance of supplemental practice expense survey data. We will continue the requirements that supplemental survey samples be drawn from the AMA Physician Masterfile whenever possible, be nationally representative, be conducted in a way that ensures confidentiality, and be based on the SMS survey instrument and protocols. We will also consider, however, non-probability sample designs that follow accepted statistical guidelines for non-probability sampling. We will allow specialties not represented in the AMA Physician Masterfile to draw samples from other nationally representative listings.

Our criteria for acceptable response rates will continue to be as flexible as possible. Our goal is to accept survey data that are representative of the practice expenses of the specialty. Representativeness can be demonstrated either by a high rate of response or evidence that shows the respondents are not significantly or systematically different from non-respondents.

In the November 1, 2000 final rule (65 FR 65383), we established a criterion that requires * * * a 90-percent confidence interval with a range of plus or minus 10 percent of the mean (that

is, 1.645 times the standard error of the mean, divided by the mean should be equal to or less than 10 percent of the mean)." It has been brought to our attention that this language could cause confusion. Instead, in this rule, we are indicating that we will accept surveys that achieve a sampling error of 0.15 or less at a confidence level of 90 percent. This change refines both the measurement of precision and the level of precision we will accept and could result in our acceptance of more surveys than the past criteria. In addition, we will allow specialties that have submitted surveys previously rejected under the present criteria to resubmit these survey to be evaluated under the revised criterion.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking and 30-Day Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on a proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We believe, in this instance, that engaging in proposed rulemaking would be contrary to the public interest. We anticipate that our revised criteria will be more effective in evaluating survey data than current criteria and will permit us to use more of the practice expense data submitted. Currently, we are aware of physician specialty groups that will be conducting a survey in 2002. If we do not publish the improved criteria contained in this interim final rule, we will continue to use the current criteria to evaluate survey data to determine physician fee schedule payments because there is insufficient time to publish proposed criteria, allow a 60-day comment period, and publish

a final rule in the **Federal Register** before the deadline for submitting supplemental survey information. There would be a delay of at least 1 year until we could apply the revised criteria to survey data to calculate practice expense RVUs. Because we believe that application of the revised criteria will produce better practice expense data for use in determining practice expense RVUs, we believe that it is in the public interest for us to apply these criteria to evaluate surveys this year. To permit surveys to be evaluated using the most appropriate criteria, we find that it is in the public interest for us to waive notice-and-comment procedure.

For this reason, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

Section 553(d) of the Administrative Procedure Act (5 U.S.C. Section 553(d)) ordinarily requires a 30-day delay in the effective date of final rules after the date of their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued.

We anticipate that our revised criteria will be more effective in evaluating survey data than current criteria and will permit us to use more of the practice expense data submitted. Currently, we are aware that physician specialty groups that will be conducting a survey in 2002. The survey data must be submitted to us by August 1, 2002. Thus, if we do not waive the proposed rule and the delay in effective date, we believe that there would be a delay of at least 1 year until we could apply the revised criteria to survey data to calculate practice expense RVUs. Because we believe that application of the revised criteria will produce better practice expense data for use in determining practice expense RVUs, we believe that it is in the public interest for us to apply these criteria to evaluate our surveys this year. To permit surveys to be evaluated using the most appropriate criteria, we find that it is in the public interest for us to waive the 30-day delay in effective date.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information

requirement, which is subject to the PRA, is submitted to the Office of Management and Budget (OMB) for review and approval.

Although this rule contains an information collection requirement, associated with the submission of a supplemental survey by any CMS-designated specialty group, we have determined that this requirement is not subject to the PRA. In particular, to date, CMS has not received any more than three surveys in a given year. Therefore, this collection requirement is not subject to the PRA as defined under 5 CFR 1320.3(3).

VI. Regulatory Impact

We have examined the impact of this interim final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the regulatory Flexibility Act (RFA) (September 16, 1980 Pub.L. 996-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act (URMA) of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of \$8.5 million or less annually (except mental health specialties). (For details, see the Small Business Administration's web site at <http://www.sba.gov/size/naicstb2-ser.pdf>). For purposes of the RFA, all physicians and non-physician providers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Since this interim final rule with comment period only modifies criteria

for physicians, non-physicians and suppliers who wish to provide data to us in computing RVUs under the physician fee schedule, there are no budgetary implications arising from this rule. The UMRA also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million or more in any year. This interim final rule with comment period will have no consequential effect on State, local, or tribal governments. We believe the private sector cost of this rule falls below these thresholds as well.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395(hh), and 1395rr(b)(1)).

2. In § 414.22, the introductory text is republished and paragraph (b)(6) is revised to read as follows:

§ 414.22 Relative value units (RVUs).

CMS establishes RVUs for physicians' work, practice expense, and malpractice insurance.

* * * * *

(b) *Practice expense RVUs.* * * *

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(6)(i) CMS establishes criteria for supplemental surveys regarding specialty practice expenses submitted to CMS that may be used in determining practice expense RVUs.

(ii) Any CMS-designated specialty group may submit a supplemental survey.

(iii) CMS will consider for use in determining practice expense RVUs for the physician fee schedule survey data and related materials submitted to CMS by August 1, 2002 to determine CY 2003 practice expense RVUs and by August 1, 2003 to determine CY 2004 practice expense RVUs.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 21, 2002.

Thomas A Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: June 5, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02-16332 Filed 6-27-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 020313055-2148-02; I.D. 021902F]

RIN 0648-A062

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Charter Vessel and Headboat Permit Moratorium

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 14 to the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (Amendment 14) and Amendment 20 to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (Amendment 20). This final rule establishes a 3-year moratorium on the issuance of charter vessel or headboat (for-hire) permits for the reef fish fishery and coastal migratory pelagics fishery in the exclusive economic zone (EEZ) of the Gulf of Mexico. Also, as a consequence of the moratorium, the current charter vessel/headboat permit for coastal migratory pelagic fish is

restructured to provide separate permits for the Gulf of Mexico and South Atlantic. In addition, NMFS informs the public of the approval by the Office of Management and Budget (OMB) of the collection-of-information requirements contained in this final rule and publishes the OMB control numbers for those collections. The intended effect of this final rule is to cap the number of for-hire vessels operating in these respective fisheries at the current level while the Gulf of Mexico Fishery Management Council (Council) evaluates the need for further management actions that may be needed to rebuild these fishery resources, and promote attainment of optimum yield.

DATES: This final rule is effective July 29, 2002, except for the revisions to §§ 622.5(b)(1) and 622.43(a)(3)(ii), which are effective December 26, 2002.

ADDRESSES: Copies of the final regulatory flexibility analysis (FRFA) and copies of a supplemental environmental assessment prepared by NMFS are available from the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Comments on the collection-of-information requirements contained in this final rule should be sent to Robert Sadler, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: Phil Steele, telephone: 727-570-5305, fax: 727-570-5583, e-mail: Phil.Steele@noaa.gov.

SUPPLEMENTARY INFORMATION: The fishery for reef fish is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (Reef Fish FMP) that was prepared by the Council. The fisheries for coastal migratory pelagic resources are managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (Coastal Migratory Pelagics FMP) that was prepared jointly by the Council and the South Atlantic Fishery Management Council. These FMPs were approved by NMFS and implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

On February 27, 2002, NMFS announced the availability of Amendments 14 and 20 and requested public comment on them (67 FR 8926).