

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare and Medicaid Services****[Document Identifier: CMS-NEW]****Agency Information Collection Activities: Proposed Collection; Comment Request****AGENCY:** Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Assessing the Division of Information and Assistance's Customer Service for Written Responses; *Form No.:* CMS-10068 (OMB# 0938-NEW); *Use:* DIA will collect information several times during the FY'02 to assess the customer service provided via written responses. DIA will conduct the written survey through mailings that will accompany actual responses. The envelopes will be sent by Release Clerks so that the actual writer has no knowledge that a particular response is being rated.; *Frequency:* Quarterly; *Affected Public:* Individuals or Households; *Number of Respondents:* 2872; *Total Annual Responses:* Total Annual Hours: 287.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on

(410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Melissa Musotto, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 20, 2002.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 02-22150 Filed 8-29-02; 8:45 am]

BILLING CODE 4120-03-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Medicare & Medicaid Services****[CMS-2136-PN]****Medicaid Program; State Allotments for Payment of Medicare Part B Premiums for Qualifying Individuals: Federal Fiscal Year 2002****AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.**ACTION:** Proposed notice.

SUMMARY: In this proposed notice, we publish our annual update on the proposed allotment we will make available to participating State agencies to pay all, or some portion of, Medicare Part B premium costs for a specified category of eligible low-income Medicare beneficiaries called qualifying individuals (QIs). These proposed expenditures, if adopted, will be made available during Federal fiscal year 2002 (beginning October 1, 2001).

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 29, 2002.

ADDRESSES: In commenting, please refer to file code CMS-2136-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail your comments (one original and three copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2136-PN, P.O. Box 8010, Baltimore, MD 21244-8010.

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 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244. (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: Robert Nakielnny, (410) 786-4466.

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 at 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. Members of the public who are interested in reviewing timely public comments are asked to schedule an appointment by calling (410) 786-9994.

I. Background**A. Before the Balanced Budget Act of 1997**

Before enactment of the Balanced Budget Act of 1997 (BBA), section 1902(a)(10)(E) of the Social Security Act (the Act) specified that State Medicaid plans must provide Medicare cost-sharing for three groups of eligible low-income Medicare beneficiaries. These three groups include: qualified Medicare beneficiaries (QMBs), specified low-income Medicare beneficiaries (SLMBs), and qualified disabled and working individuals (QDWMs).

A QMB is an individual entitled to Medicare Part A (Hospital Insurance) with an income that falls at or below the Federal poverty level and resources below \$4,000 for an individual and \$6,000 for a couple. An SLMB is an

individual who meets the QMB criteria, except that his or her income is between a State-established level (at or below the Federal poverty level) and 120 percent of the Federal poverty level. A QDWI is an individual who is entitled to enroll in Medicare Part A, whose income does not exceed 200 percent of the Federal poverty level for a family of the size involved, whose resources do not exceed twice the amount allowed under the Supplementary Security Income program, and who is not otherwise eligible for Medicaid.

The definition of Medicare cost-sharing at section 1905(p)(3) of the Act includes payment for Medicare premiums, although QDWIs only qualify to have Medicaid pay their Medicare part A premiums.

B. After Enactment of the Balanced Budget Act of 1997

Section 4732 of the BBA amended section 1902(a)(10)(E) of the Act to require that States provide for Medicaid payment of all, or a portion of, Medicare Part B (Supplementary Medical Insurance) premiums, during the period beginning January 1998 through December 2002, for selected members of two eligibility groups of low-income Medicare beneficiaries, referred to as qualifying individuals (QIs).

Under section 1902(a)(10)(E)(iv)(I) of the Act, State agencies are required to pay the full amount of the Medicare Part B premium for selected QIs who would be QMBs except that their income level is at least 120 percent but less than 135 percent of the Federal poverty level for a family of the size involved. These individuals cannot otherwise be eligible for medical assistance under the approved State Medicaid plan.

The second group of QIs, under section 1902(a)(10)(E)(iv)(II) of the Act, includes Medicare beneficiaries who would be QMBs except that their income is at least 135 percent but less than 175 percent of the Federal poverty level for a family of the size involved. These QIs may not be otherwise eligible for Medicaid under the approved State plan, but are eligible for a portion of Medicare cost-sharing consisting only of a percentage of the increase in the Medicare Part B premium attributable to

the shift of Medicare home health coverage from Part A to Part B (as provided in section 4611 of the BBA).

Section 4732(c) of the BBA also added section 1933 of the Act, which specifies the provisions for State coverage of the Medicare cost-sharing for additional low-income Medicare beneficiaries.

Section 1933(a) of the Act specifies that a State agency must provide, through a State plan amendment, for medical assistance to pay for the cost of Medicare cost-sharing on behalf of QIs who are selected to receive assistance.

Section 1933(b) of the Act sets forth the rules that State agencies must follow in selecting QIs and providing payment for Medicare Part B premiums.

Specifically, the State agency must permit all QIs to apply for assistance and must select individuals on a first-come, first-served basis in the order in which they apply. Under section 1933(b)(2)(B) of the Act, when selecting persons who will receive assistance in calendar years after 1998, State agencies must give preference to those individuals who received assistance as QIs, QMBs, SLMBs, or QDWIs in the last month of the previous year, and who continue to be QIs, or become QIs.

Under section 1933(b)(4) of the Act, persons selected to receive assistance in a calendar year are entitled to receive assistance for the remainder of the year, but not beyond, as long as they continue to qualify. The fact that an individual is selected to receive assistance at any time during the year does not entitle the individual to continued assistance for any succeeding year. Because the allotment to the States is limited by law, section 1933(b)(3) of the Act provides that the State agency must limit the number of QIs so that the amount of assistance provided during the year is approximately equal to a State's allotment for that year.

Section 1933(c) of the Act limits the total amount of Federal funds available for payment of Part B premiums each fiscal year and specifies the formula to be used to determine an allotment for each State from this total amount. For State agencies that execute a State plan amendment in accordance with section 1933(a) of the Act, a total of \$1.5 billion was allocated over 5 years as follows:

\$200 million in FY 1998; \$250 million in FY 1999; \$300 million in FY 2000; \$350 million in FY 2001; and \$400 million in FY 2002.

The Federal matching rate for Medicaid payment of Medicare Part B premiums for QIs is 100 percent for expenditures up to the amount of the State's allotment. No Federal matching funds are available for expenditures in excess of the State's allotment amount. Administrative expenses associated with the payment of Medicare Part B premiums for QIs remain at the 50 percent matching level and may not be taken from the State's allotment.

The amount available for each fiscal year is to be allocated among States according to the formula set forth in section 1933(c)(2) of the Act. The formula provides for an amount to each State agency that is based on each State's share of the Secretary's estimate of the ratio of—(1) An amount equal to the sum of the following:

(a) Twice the total number of individuals who meet all but the income requirements for QMBs, whose incomes are at least 120 percent but less than 135 percent of the Federal poverty level, and who are not otherwise eligible for Medicaid; and

(b) The total number of individuals in the State who meet all but the income requirements for QMBs, whose incomes are at least 135 percent but less than 175 percent of the Federal poverty level, and who are not otherwise eligible for Medicaid;

(2) The sum of all of these individuals under item (1) for all eligible States.

II. Provisions of This Proposed Notice

This notice announces the proposed allotments to be made available to individual States for Federal fiscal year 2002 for the Medicaid payment of Medicare Part B premiums for QIs identified under sections 1902(a)(10)(E)(iv)(I) and (II) of the Act. The formula used to calculate these allotments was described in detail in the January 26, 1998 **Federal Register** (63 FR 3752, 3754) and, except for the incorporation of the latest data, has been used here without changes.

FY 2002 STATE ALLOTMENTS FOR PAYMENT OF PART B PREMIUMS UNDER SEC. 4732 OF THE BBA OF 1997

State	(a) M1 ¹	(b) M2 ²	(c) 2 × (a) + (b)	State share of (c) (percent)	State FY 2002 (\$000) allocation
AK	1	3	5	0.08	\$321
AL	25	68	118	1.90	7,584
AR	23	46	92	1.48	5,913
AZ	20	63	103	1.65	6,620

FY 2002 STATE ALLOTMENTS FOR PAYMENT OF PART B PREMIUMS UNDER SEC. 4732 OF THE BBA OF 1997—
Continued

State	(a) M1 ¹	(b) M2 ²	(c) 2 × (a) + (b)	State share of (c) (percent)	State FY 2002 (\$000) allocation
CA	114	307	535	8.60	34,383
CO	11	37	59	0.95	3,792
CT	11	55	77	1.24	4,949
DC	3	5	11	0.18	707
DE	5	10	20	0.32	1,285
FL	114	249	477	7.66	30,656
GA	31	69	131	2.10	8,419
HI	3	13	19	0.31	1,221
IA	20	49	89	1.43	5,720
ID	7	18	32	0.51	2,057
IL	38	138	214	3.44	13,753
IN	46	88	180	2.89	11,568
KS	12	33	57	0.92	3,663
KY	19	65	103	1.65	6,620
LA	27	57	111	1.78	7,134
MA	40	85	165	2.65	10,604
MD	26	49	101	1.62	6,491
ME	7	23	37	0.59	2,378
MI	42	127	211	3.39	13,560
MN	27	46	100	1.61	6,427
MO	29	60	118	1.90	7,584
MS	17	44	78	1.25	5,013
MT	5	11	21	0.34	1,350
NC	49	89	187	3.00	12,018
ND	5	13	23	0.37	1,478
NE	9	34	52	0.84	3,342
NH	3	14	20	0.32	1,285
NJ	35	109	179	2.88	11,504
NM	11	28	50	0.80	3,213
NV	7	23	37	0.59	2,378
NY	92	233	417	6.70	26,799
OH	52	167	271	4.35	17,416
OK	14	65	93	1.49	5,977
OR	15	32	62	1.00	3,985
PA	81	187	349	5.61	22,429
RI	7	13	27	0.43	1,735
SC	34	58	126	2.02	8,098
SD	4	13	21	0.34	1,350
TN	37	61	135	2.17	8,676
TX	82	218	382	6.14	24,550
UT	7	16	30	0.48	1,928
VA	45	83	173	2.78	11,118
VT	3	8	14	0.22	900
WA	21	56	98	1.57	6,298
WI	24	87	135	2.17	8,676
WV	11	44	66	1.06	4,242
WY	3	7	13	0.21	835
Total	1374	3476	6224	100.00	400,000

¹ Three-year average (1999–2001) of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 120% but less than 135% of the Federal Poverty Level (FPL).

² Three-year average (1999–2001) of number (000) of Medicare beneficiaries in State who are not enrolled in Medicaid but whose incomes are at least 135% but less than 175% of the Federal Poverty Level (FPL).

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 proposed notice, and, if we proceed

with a subsequent document, we will respond to the comments in that document.

IV. Regulatory Impact Statement

We have examined the impact of this proposed notice as required by Executive Order 12866 (September 1993, Regulatory planning and review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354),

section 1102(b) of the Act, the Unfunded Mandates Reform Act 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). A regulatory impact analysis (RIA) must be prepared for major rules with economic effects of \$100 million or more annually. We have determined this to be a major rule. It provides \$400 million to a specialized category of low-income Medicare beneficiaries.

The RFA requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, States and individuals are not considered to be small entities.

This proposed notice would allocate, among the States, Federal funds to provide Medicaid payment for Medicare Part B premiums for QIs. The total amount of Federal funds available during a Federal fiscal year and the formula for determining individual State allotments are specified in the law. Because the formula for determination of State allotments is specified in the statute, there were no other options to be considered. Therefore, we have applied the statutory formula for the State allotments except for the use of specified data. Because the data specified in the law were not available, we have used comparable data from the U.S. Census Bureau on the number of possible QIs in the States, as described in detail in the January 26, 1998 **Federal Register**. Since the statutory formula calls for an estimate of individuals who could qualify for QI status rather than the number of individuals who actually have that status, the exact numbers of those individuals will always be uncertain. These new allotments for FY 2002 incorporate the latest data from the U.S. Census Bureau from 1999 to 2001, as specified in the footnotes to the preceding table.

We believe the statutory provisions that would be implemented in this proposed notice would have a positive effect on States and individuals. Federal funding at the 100 percent matching rate is available for Medicare cost-sharing for Medicare Part B premium payments for selected QIs, and a greater number of low-income Medicare beneficiaries would be eligible to have their Medicare Part B premiums paid under Medicaid.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 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 a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act, because we have determined and certify that this proposed notice would 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.

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104-4, also requires that agencies assess anticipated costs and benefits before issuing any proposed rule and a final rule preceded by a proposed rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or any the private sector, or \$110 million or more. This notice would have no consequential effect on the governments mentioned or on the private sector.

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism. Because this proposed notice would simply provide notice of funding ceilings, as determined under the statute, we have determined that this proposed notice would not significantly affect the rights, roles, and responsibilities of States.

In accordance with the provisions of Executive Order 12866, this proposed notice with comment period was reviewed by the Office of Management and Budget (OMB).

Authority: Sections 1902(a)(10)(E) and 1933 of the Social Security Act (42 U.S.C. 1396a(a)(10)(E) and 1396x).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: April 28, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 26, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02-22228 Filed 8-29-02; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0102]

Agency Information Collection Activities; Announcement of OMB Approval; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 28, 2002 (67 43633), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0374. The approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: August 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-22115 Filed 8-29-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0159]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Focus Groups as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.