

II. Copies of the Charter

You may obtain a copy of the charter for the PPAC by submitting a request to Diana Motsiopoulos, Administrative Coordinator, Centers for Medicare & Medicaid, 7500 Security Blvd., Mail Stop: C4-11-27, Baltimore, MD 21244-1850, (410) 786-3379 or E-mail the request to dmotsiopoulos@cms.hhs.gov. A copy of the charter will also be available on the Internet at <http://www.cms.hhs.gov/faca/ppac/default.asp>.

Authority: Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and (5 U.S.C. App. 2)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 11, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03-16055 Filed 6-26-03; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-4062-N]

Medicare and Medicaid Programs; Solicitation for Information on the Hospital CAHPS

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice seeks input and recommendations regarding an initiative that the Department of Health and Human Services (DHHS) plans to use to create a standard instrument, sampling, and data collection protocol that hospitals can use to collect comparable data for use in publicly reporting hospital patients' perspectives on the care they received. This survey is being developed and tested by the Agency for Healthcare Research and Quality (AHRQ) in conjunction with the CAHPS® (formerly known as the Consumer Assessment of Health Plans Survey). The initiative is being called "Hospital CAHPS" or "HCAHPS." In this notice, we are soliciting public input on the draft HCAHPS survey instrument and recommendations for the survey administration.

DATES: We will consider comments on the draft HCAHPS survey instrument and recommendations for the survey

administration if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 28, 2003.

ADDRESSES: Comments should be mailed to the following address: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Attention: Elizabeth Goldstein, Director for the Division of Beneficiary Analysis, Mail Stop: S1-13-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. E-mail comments should be sent to the following address: egoldstein@cms.hhs.gov.

General Information: Comments may be in the form of a letter or e-mail. Please refer to file code CMS-4062-N when submitting comments and include name, title, organization, mailing address, telephone number, fax number, and e-mail address.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmissions. Comments postmarked after the closing date, or postmarked on or before the closing date but not received in time for the review, will be considered late comments.

FOR FURTHER INFORMATION CONTACT: Elizabeth Goldstein, (410) 786-6665 or by e-mail at egoldstein@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A key priority for the Secretary of HHS and our Administrator is hospital public reporting. Therefore, we are currently working with the AHRQ to develop the HCAHPS standard instrument and data collection protocol to collect comparable data to support public reporting of hospital patients' perspectives on inpatient hospital care they received.

AHRQ has initiated a rigorous process to develop a draft of the HCAHPS survey instrument. On July 24, 2002, AHRQ published a "Notice of Request for Measures" in the **Federal Register** (67 FR 48477) soliciting the submission of existing instruments measuring patients' perspectives on care. In addition, AHRQ conducted an exhaustive review of existing literature, conducted cognitive testing with sample survey respondents, and obtained stakeholder input on the process of developing the draft HCAHPS survey instrument.

On February 5, 2003, we published a collection of information requirement notice in the **Federal Register** (68 FR 5889), soliciting input on a draft HCAHPS survey instrument. In this notice, we are soliciting input on the same draft HCAHPS survey instrument

that was published on February 5, 2003, in the **Federal Register** and are providing a 30 day comment period to allow interested parties another opportunity to comment on the draft HCAHPS survey instrument. We will consider both sets of comments when revising the HCAHPS survey instrument.

In addition, we are currently testing the same draft HCAHPS survey instrument as part of CMS's 3-State hospital pilot project in Maryland, New York, and Arizona. (See our Web site at <http://www.cms.hhs.gov/quality/hospital> for more information on the 3-State hospital pilot project and the draft HCAHPS survey instrument).

Through the 3-State hospital pilot we will also assess the draft HCAHPS survey instrument. Results will be used to examine the reliability and validity of the draft HCAHPS items, and identify the items that are most useful for public reporting. Based on the results of the 3-State hospital pilot and public input received regarding the draft items, AHRQ will revise the HCAHPS survey instrument. We anticipate that the revised HCAHPS survey instrument would be significantly shorter than the current version.

At the end of the 3-State hospital pilot process and revisions pursuant to public comments, DHHS should have a standard, well-tested instrument for measuring patients' perspectives on hospital care that can be used for comparative public reporting. The 3-State hospital pilot and draft HCAHPS survey instrument is currently designed for all hospital patients 18 years old and over, excluding psychiatric patients. We expect that the final HCAHPS survey instrument would be put in the public domain for use by hospitals or other interested parties.

HCAHPS can be seen as a core set of questions to which individual hospitals can add their own specific questions. HCAHPS is designed to produce data for comparative public reporting to support consumer choice. The HCAHPS survey instrument will complement, not replace data currently collected that support improvement in internal hospital customer services and related activities.

It is our intent to create a process for data collection that can generate data useful for comparative public reporting and that can be used in conjunction with existing survey processes used for quality improvement. We are reviewing options that would allow us to meet our public reporting goals while allowing flexibility in survey administration. As we consider various options, we expect, at a minimum, to be able to

accommodate administration by mail or telephone.

II. Provisions of this Notice

A. Purpose

The purpose of this notice is to solicit comments and recommendations on the draft HCAHPS survey instrument and implementation options.

B. Solicitation Regarding HCAHPS

As previously mentioned, the draft HCAHPS survey instrument was published for public comment on February 5, 2003, in the **Federal Register** and is currently being tested as part of CMS's 3-State hospital pilot project in Maryland, New York, and Arizona. In this notice, we are soliciting input on the same draft HCAHPS survey instrument and are providing a 30 day comment period to allow interested parties another opportunity to submit comments to be used in revising the HCAHPS survey instrument. We are also soliciting input on the number of questions that should be in the revised HCAHPS survey instrument. (See addendum).

C. Input on Implementation Options

We are soliciting input and recommendations for the survey administration, including sampling and data collection methods. We request that those providing comments discuss any survey biases that may be present in the approach they suggest (for example, differential mode effects) and how such biases might be addressed to allow fair and meaningful comparisons between hospitals. Some of the specific areas that we are interested in receiving input on are discussed below. In addition to the areas specified below, we are also seeking input on any issues that would affect the implementation of HCAHPS. For example, we are interested in any best practices in case-mix adjustments to control for differences in hospital patient populations.

1. Mode of Administration

Currently, there is wide variation in administration protocols including: (1) Mail, telephone, and other modes (such as interactive voice recognition); (2) number of follow-up surveys sent or telephone calls made; (3) Computer Assisted Telephone Interviewing (CATI) scripts; (4) refusal conversion protocols; (5) pre-notification and cover letter language; and (6) quality control procedures.

We are soliciting input regarding best practices in mail, telephone, or other modes of administration. We would appreciate comments regarding how we

can provide flexibility in survey administration, but at the same time ensure objective comparisons between hospitals. We would also appreciate suggestions regarding ways to adjust for any biases that may be present in the approaches suggested.

2. Frequency of Data Collection

There is currently variation in terms of how often hospitals survey their patients. Some hospitals continuously survey their patients, while others do it periodically. As part of our data collection options for hospitals, we would like to ensure that we accurately reflect the mix of patients served by a hospital, capture sufficient samples, and provide the least disruption to current survey operations. Therefore, we are soliciting input on whether data collection should be ongoing or provided at a specific time (for example, at one point of time in a given year) and the pros and cons of the approach suggested.

3. Sampling

Currently, there are differences across hospitals in terms of how the sampling frame is developed and who is included in the sample. Therefore, we are soliciting input regarding what issues need to be considered as a sampling design is developed and the appropriate exclusions from the sample. We are soliciting this input to develop a sampling approach that would allow for a meaningful comparison across hospitals.

4. Time After Discharge

Survey vendors and hospitals currently differ on how quickly patients are surveyed following discharge. We are soliciting input regarding how quickly discharge lists are available; how soon after discharge is it feasible to survey patients; and what is the quality of data contained on the discharge lists.

For the national implementation of HCAHPS, there will be distinct roles for hospitals, survey vendors, and the government. Hospitals and vendors will be responsible for data collection, including: (1) Developing a sampling frame of relevant discharges; (2) drawing the sample of discharges to be surveyed; (3) collecting survey data from sampled discharges; and (4) submitting HCAHPS data to CMS in a standard format. We anticipate that there will be multiple survey vendors, including current survey vendors, who would be able to administer HCAHPS. As will be discussed in a separate document, hospitals will not be required to use a vendor for

administration of HCAHPS. However, we anticipate hospitals that choose to administer HCAHPS without the use of a vendor to be able to follow all HCAHPS standards and specifications related to administration of the HCAHPS survey instrument. We will make the HCAHPS survey instrument freely available in the public domain.

The government will be responsible for support of the HCAHPS initiative and public reporting. The government responsibility would include: (1) Providing technical assistance; (2) ensuring the integrity of data collection; (3) accumulating HCAHPS data from individual hospitals; (4) producing risk-adjusted hospital-level estimates; (5) conducting research on the presentation of data for public reporting; and (6) reporting publicly the comparative hospital data.

D. Submission Process

We note, that we will not respond individually to all comments, but will consider all suggestions submitted. To facilitate handling of submissions, the commenter must submit the following information: (1) Name; (2) title; (3) organization; (4) mail address; (5) telephone number; (6) fax number; and (7) e-mail address.

For each of the implementation issues described above or any other issues related to survey implementation, we request that the commenter provide in their response any comments and evidence regarding the effectiveness of the proposed implementation approach.

E. Evaluation Process

Based on the comments and input we receive on the 3-State hospital pilot, the draft HCAHPS survey instrument, and the implementation options, we will develop a draft survey administration strategy. Our intent is that the strategy will support our public reporting goals and allow some level of flexibility in survey administration. All final HCAHPS materials will be put in the public domain for use by hospitals nationally.

Authority: Section 1138 of the Social Security Act (42 U.S.C. 1320b-8).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; Program No. 93.774, Medicare-Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: June 17, 2003.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

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(ADDENDUM)**Hospital CAHPS®
CMS Pilot Test Questionnaire****Draft—Not for Circulation****This questionnaire may not be used
without permission**

Some items in this questionnaire drew ideas and phrases from items submitted by interested organizations in response to the "Call for Measures" published on July 24, 2002. However, the precise wording of most of the items in this questionnaire is distinct from the wording of submitted items.

We thank the following organizations that generously submitted questionnaire items to assist this endeavor:

Avatar International Inc.
Edge Health Care Research, Inc.
Healthcare Financial Management Association
Jackson Organization
National Research Corporation
Peace Health
Press Ganey Associates
Professional Research Consultants
SSM Health Care

This Hospital CAHPS® CMS Pilot Test Questionnaire is being tested under the direction of the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare and Medicaid Services (CMS) and may not be used by any other individual or organization for any other purposes without the written permission. Upon request, AHRQ will seek requisite permission from authors, as appropriate. Please contact Charles Darby at AHRQ, cdarby@ahrq.gov, or 301 594-2050 with such requests.

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SURVEY INSTRUCTIONS

- ◆ Answer all the questions by checking the box to the left of your answer.
- ◆ You are sometimes told to skip over some questions in this survey. When this happens you will see an arrow with a note that tells you what question to answer next, like this:

Yes → *If Yes, Go to Question 1 on Page 1*

No

{This box should be placed on the Cover Page}

All information that would let someone identify you or your family will be kept private. {SPONSOR NAME} will not share your personal information with anyone without your OK. You may choose to answer this survey or not. If you choose not to, this will not affect the benefits you get.

You may notice a number on the cover of this survey. This number is ONLY used to let us know if you returned your survey so we don't have to send you reminders.

If you want to know more about this study, please call XXX.

1. Our records show that you were discharged from [FACILITY NAME] on or about [DISCHARGE DATE]. Is that right?

- Yes
 No → If No, Stop and return this survey.

Please answer the questions in this survey about this stay at [FACILITY NAME]. Do not include any other hospital stay in your answers.

2. Which option below best describes the reason for this hospital stay?

- Surgery
 Childbirth (including caesarian section)
 Other medical reason

3. About how many nights was this hospital stay?

Enter number of nights: _____

YOUR CARE FROM NURSES

4. During this hospital stay, how often did nurses treat you with courtesy and respect?

- Never
 Sometimes
 Usually
 Always

5. During this hospital stay, how often did nurses listen carefully to you?

- Never
 Sometimes
 Usually

- Always

6. During this hospital stay, how often did nurses explain things in a way you could understand?

- Never
 Sometimes
 Usually
 Always

7. During this hospital stay, how often did nurses spend enough time with you?

- Never
 Sometimes
 Usually
 Always

8. During this hospital stay, did you press the call button?

- Yes
 No → If No, Go to Question 10

9. After you pressed the call button, how often did you get help as soon as you wanted it?

- Never
 Sometimes
 Usually
 Always

10. We want to know your rating of the care you received from nurses during this hospital stay

Using any number from 0 to 10 where 0 is the worst possible care and 10 is the best possible care, what number would you give the care you got from all the nurses who treated you?

- 0 Worst possible nursing care
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10 Best possible nursing care

YOUR CARE FROM DOCTORS

11. During this hospital stay, how often did doctors treat you with courtesy and respect?
- 1 Never
 2 Sometimes
 3 Usually
 4 Always
12. During this hospital stay, how often did doctors listen carefully to you?
- 1 Never
 2 Sometimes
 3 Usually
 4 Always
13. During this hospital stay, how often did doctors explain things in a way you could understand?
- 1 Never
 2 Sometimes
 3 Usually
 4 Always
14. During this hospital stay, how often did doctors spend enough time with you?
- 1 Never
 2 Sometimes

- 3 Usually
 4 Always

15. We want to know your rating of the care you received from doctors during this hospital stay.

Using any number from 0 to 10 where 0 is the worst possible care and 10 is the best possible care, what number would you give the care you got from all the doctors who treated you?

- 0 Worst possible doctor care
 1
 2
 3
 4
 5
 6
 7
 8
 9
 10 Best possible doctor care

THE HOSPITAL ENVIRONMENT

16. During this hospital stay, how often was the temperature in your room comfortable?
- 1 Never
 2 Sometimes
 3 Usually
 4 Always
17. During this hospital stay, how often were your room and bathroom kept clean?
- 1 Never
 2 Sometimes
 3 Usually
 4 Always

18. During this hospital stay, how often was the area around your room quiet at night?

1 Never
 2 Sometimes
 3 Usually
 4 Always

YOUR EXPERIENCES IN THIS HOSPITAL

19. During this hospital stay, did you need help from doctors, nurses or other hospital staff with bathing, washing or keeping clean?

1 Yes
 2 No → If No, Go to Question 21

20. How often did you get help with bathing, washing or keeping clean as soon as you wanted?

1 Never
 2 Sometimes
 3 Usually
 4 Always

21. During this hospital stay, did you need help from doctors, nurses or other hospital staff in getting to the bathroom or in using a bedpan?

1 Yes
 2 No → If No, Go to Question 23

22. How often did you get help in getting to the bathroom or in using a bedpan as soon as you wanted?

1 Never
 2 Sometimes
 3 Usually

4 Always

23. At any time during this stay, did you share a hospital room with one or more other patients?

1 Yes
 2 No → If No, Go to Question 25

24. How often did doctors, nurses, and other hospital staff make sure that you had privacy when they took care of you or talked to you?

1 Never
 2 Sometimes
 3 Usually
 4 Always

25. During this hospital stay, how often did doctors, nurses or other hospital staff involve you in decisions about your treatment as much as you wanted?

1 Never
 2 Sometimes
 3 Usually
 4 Always

26. During this hospital stay, did your family or friends call or come to visit you?

1 Yes
 2 No → If No, Go to Question 28

27. During this hospital stay, how often did your family and friends receive the help they needed when they called or visited the hospital?

1 Never
 2 Sometimes
 3 Usually
 4 Always

28. During this hospital stay, when doctors, nurses, or other hospital staff first came to care for you, how often did they introduce themselves?

- 1 Never
 2 Sometimes
 3 Usually
 4 Always

29. Did you have pain during this hospital stay?

- 1 Yes
 2 No

30. During this hospital stay, did you have to ask for pain medicine?

- 1 Yes
 2 No → If No, Go to Question 32

31. How often did doctors, nurses or other hospital staff respond quickly when you asked for pain medicine?

- 1 Never
 2 Sometimes
 3 Usually
 4 Always

32. During this hospital stay, how often was your pain well controlled?

- 1 Never
 2 Sometimes
 3 Usually
 4 Always

33. During this hospital stay, how often did the doctors, nurses or other hospital staff do everything they could to help you with your pain?

- 1 Never
 2 Sometimes
 3 Usually
 4 Always

34. We want to ask you about medical procedures and tests, for example, drawing blood, taking x-rays, and applying and removing stitches and bandages.

During this hospital stay did you have any medical procedures or tests?

- 1 Yes
 2 No → If No, Go to Question 36

35. How often were these tests and procedures done without causing you too much pain?

- 1 Never
 2 Sometimes
 3 Usually
 4 Always

36. During this hospital stay, were you given any new medicine that you had not taken before?

- 1 Yes
 2 No → If No, Go to Question 42

37. Before giving you any new medicine, how often did doctors, nurses, or other hospital staff tell you the name of the medicine?

- 1 Never
 2 Sometimes
 3 Usually
 4 Always

38. Before giving you any new medicine, how often did doctors,

nurses, or other hospital staff tell you what the medicine was for?

- Never
 Sometimes
 Usually
 Always

39. Before giving you any new medicine, how often did doctors, nurses, or other hospital staff ask you if you were taking any other medicines or supplements?

- Never
 Sometimes
 Usually
 Always

40. Before giving you any new medicine, how often did doctors, nurses, or other hospital staff ask if you were allergic to any medicines?

- Never
 Sometimes
 Usually
 Always

41. Before giving you any new medicine, how often did doctors, nurses, or other hospital staff describe possible side effects of the medicine in a way you could understand?

- Never
 Sometimes
 Usually
 Always

ADMISSIONS

42. During this hospital stay, were you admitted to this hospital through the Emergency Room?

- Yes

- No

43. Think about when you were admitted to the hospital for this stay. Were there any unreasonable delays during the admission process?

- Yes
 No

44. A living will is a signed document that gives instructions about the kinds of medical treatment people want, or do not want, if they are not able to speak for themselves.

When you were admitted to the hospital for this stay, were you asked if you had a living will?

- Yes
 No

DISCHARGE

45. After you left the hospital, did you go directly to your own home, to someone else's home, or to another health facility?

- Own Home
 Someone Else's Home
 Another Health Facility → If Another, Go to Question 52

46. After you left the hospital, did your health condition limit what you were able to do in any way?

- Yes
 No → If No, Go to Question 49

47. Before you left the hospital, did you get information in writing about what activities you could and could not do?

- Yes
- No

48. Before you left the hospital, did someone talk with you about whether you would have the help you needed when you were discharged?

- Yes
- No

49. Before you left the hospital, did you get information in writing about what symptoms or health problems to look out for after you were discharged?

- Yes
- No

50. Before you left the hospital, were you told to take any medicine at home that you had not taken before this hospital stay?

- Yes
- No → If No, Go to Question 52

51. Before you left the hospital, did you get information in writing about how to take this medicine at home?

- Yes
- No

OVERALL RATING OF HOSPITAL

Please answer the following questions about the stay at the hospital _____ shown on the cover. Do not include any other hospital stays in your answer.

52. We want to know your overall rating of this hospital.
Using any number from 0 to 10,

where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital?

- 0 Worst hospital possible
- 1
- 2
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10 Best hospital possible

53. Would you recommend this hospital to your friends and family?

- Definitely no
- Probably no
- Probably yes
- Definitely yes

54. What did you like most about the care you received during this hospital stay?

55. If you could change one thing about the care you received during this hospital stay, what would it be?

ABOUT YOU

56. In general, how would you rate your overall health now?

- 1 Excellent
 2 Very good
 3 Good
 4 Fair
 5 Poor

57. In general, how would you rate your overall mental or emotional health now?

- 1 Excellent
 2 Very good
 3 Good
 4 Fair
 5 Poor

58. What is your age now?

- 1 18 to 24
 2 25 to 34
 3 35 to 44
 4 45 to 54
 5 55 to 64
 6 65 to 74
 7 75 to 79
 8 80 or older

59. Are you male or female?

- 1 Male
 2 Female

60. What is the highest grade or level of school that you have completed?

- 1 8th grade or less
 2 Some high school, but did not graduate
 3 High school graduate or GED

- 4 Some college or 2-year degree
 5 4-year college graduate
 6 More than 4-year college degree

61. Are you of Hispanic or Latino origin or descent?

- 1 Yes, Hispanic or Latino
 2 No, not Hispanic or Latino

62. What is your race? Please choose one or more.

- 1 White
 2 Black or African-American
 3 Asian
 4 Native Hawaiian or other Pacific Islander
 5 American Indian or Alaskan Indian or Alaskan Native
 8 Other (please print):

63. What language do you mainly speak at home?

- 1 English
 2 Spanish
 8 Some other language (please print):

64. Including this hospital stay, how many hospital stays did you have in the last 12 months?

- 1 One
 2 Two
 3 Three
 4 Four or more stays

65. Did someone help you complete this survey?

- ¹ Yes → **Go to Question 66**
- ² No → **Please return the survey in the postage-paid envelope.**

**66. How did that person help you?
Check all that apply.**

- ¹ Read the questions to me
- ² Wrote down the answers I gave
- ³ Answered the questions for me
- ⁴ Translated the questions into my language
- ⁵ Helped in some other way
(Please print)

THANK YOU

Please return the completed survey in the postage-paid envelope.

[FR Doc. 03-16057 Filed 6-26-03; 8:45 am]

BILLING CODE 4120-01-C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9017-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—January 2003 Through March 2003

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from January 2003 through March 2003, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption numbers approved by the Food and Drug Administration that potentially may be covered under Medicare. Finally, this notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are also including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. (See Section III of this notice for how to obtain listed material.)

Questions concerning items in Addendum III may be addressed to Karen Bowman, Office of Strategic Operations and Regulatory Affairs,

Centers for Medicare & Medicaid Services, C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-5252.

Questions concerning national coverage determinations in Addendum V should be directed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-0261.

Questions concerning Investigational Device Exemptions items in Addendum VI may be addressed to Sharon Hippler, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C5-13-27, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-4633.

Questions concerning approval numbers for collections of information in Addendum VII may be addressed to Dawn Willingham, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-6141.

Questions concerning all other information may be addressed to Margie Teeters, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5-13-18, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-4678.

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients. Administration of these programs involves (1) furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, fiscal intermediaries and carriers that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act

(the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the 3-month time frame.

II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations, national coverage determinations, and Food and Drug Administration-approved investigational device exemptions published during the timeframe to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) published in 1988, and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare Coverage Issues Manual (CIM) may wish to review the August 21, 1989 publication (54 FR 34555). Those interested in the procedures used in making national coverage determinations under the Medicare program may review the April 27, 1999 publication (64 FR 22619).

To aid the reader, we have organized and divided this current listing into six addenda:

- Addendum I lists the publication dates of the most recent quarterly listings of program issuances.
- Addendum II identifies previous **Federal Register** documents that contain a description of all previously published CMS Medicare and Medicaid manuals and memoranda.
- Addendum III lists a unique CMS transmittal number for each instruction in our manuals or Program Memoranda and its subject matter. A transmittal may consist of a single instruction or many. Often, it is necessary to use information in a transmittal in conjunction with information currently in the manuals.