Form No.: CMS–0029/0030 (OMB# 0938–0074).

Use: The Form CMS–29 is utilized as an application to be completed by suppliers of RHC services requesting participation in the Medicare/Medicaid programs. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Online Survey and Certification and Reporting System (OSCAR) by the CMS Regional Offices (RO). The Form CMS–30 is an instrument used by the State survey agency to record data collected in order to determine RHC compliance with individual conditions of participation and to report it to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction (keypunching) and retrieval into OSCAR at the CMS ROs. The form includes basic information on compliance (i.e., met, not met and explanatory statements) and does not require any descriptive information regarding the survey activity itself.

Frequency: Annually.

Affected Public: State, Local, or Tribal Government.

Number of Respondents: 661.

Total Annual Responses: 661; Total Annual Hours: 1,157.

2. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: State Medicaid Eligibility Quality Control (MEQC) Sampling Plan and Supporting Regulations in 42 CFR 431.800–431.865.

Form No.: CMS–317 (OMB# 0938–0146).

Use: The State MEQC sampling plan is necessary for CMS to monitor the States' operation of the MEQC system for States performing the traditional sampling process. The sampling plan includes all data involved in the States' sample selection process—population sizes and sample frame lists, sample sizes, sample selection procedures, and claim collection procedures.

Frequency: Semi-annually.

Affected Public: State, Local, or Tribal Government.

Number of Respondents: 55.

Total Annual Responses: 110.

Total Annual Hours: 2,640.

3. *Type of Information Collection Request:* Extension of a currently approved collection;

Title of Information Collection: State Medicaid Eligibility Quality Control (MEQC) Sample Section Lists and Supporting Regulations in 42 CFR 431.800—431.865.

Form No.: CMS–0319 (OMB# 0938–0147).

Use: The sample selection lists contain identifying information on Medicaid beneficiaries and is the basis for the cases that States review to determine the accuracy of the Medicaid eligibility determinations. The Regional Office uses this list to monitor State review activity.

Frequency: Monthly.

Affected Public: State, Local or Tribal Government.

Number of Respondents: 55.

Total Annual Responses: 660.

Total Annual Hours: 5,280.

4. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: End Stage Renal Disease Death Notification 42 CFR 405.2133.

Form No.: CMS–2746 (OMB# 0938–0448).

Use: This form is completed by all Medicare approved ESRD facilities upon the death of an ESRD patient. The form's primary purpose is to collect fact and cause of death. Reports of deaths are used to show cause of death and demographic characteristics of these patients.

Frequency: On occasion.

Affected Public: Business or other for-profit, Not-for-profit institutions, Federal Government.

Number of Respondents: 4,000.

Total Annual Responses: 56,258.

Total Annual Hours: 9,564.

5. *Type of Information Collection Request:* Extension of a currently approved collection.

Title of Information Collection: Medicare Telephone Customer Satisfaction Survey.

Form No.: CMS–R–293 (OMB# 0938–0780).

Use: In response to the National Partnership for Reinventing Government and Government Performances and Results Act (GPRA), CMS is implementing a number of initiatives to measure and then improve the customer service that is provided by Medicare Call Centers, that service over 21 million calls annually.

Frequency: On occasion, simi-annually, other (single 800# survey).

Affected Public: Individuals or Households; Number of Respondents: 50,000.

Total Annual Responses: 50,000.

Total Annual Hours: 3,500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp*, 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 31, 2002.

John P. Burke, III,

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

[FR Doc. 02–28423 Filed 11–7–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Maryland State Plan Amendment 02–05

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on December 19, 2002, Suite 216, The Public Ledger Building, 150 S. Independence Mall West, Philadelphia, Pennsylvania 19106, at 10 a.m., to reconsider our decision to disapprove Maryland State Plan Amendment 02–05.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by (15 days after publication).

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, Office of Hearings, Centers for Medicare & Medicaid Services, Suite L, 2520 Lord Baltimore Drive, Baltimore, Maryland 21244–2670, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove Maryland State Plan Amendment (SPA) 02–05. This SPA was disapproved on August 26, 2002.

In this amendment, Maryland proposes to cover targeted case management services for abused and neglected children under foster care. At issue is whether the Centers for Medicare & Medicaid Services properly

concluded as a basis for disapproving the amendment that: (1) The State had not demonstrated that the proposed services were within the statutory definition of case management services found in section 1915(g)(2) of the Social Security Act (the Act); (2) the proposed services are available without charge to the user and thus payment under the amendment is not reasonable and necessary and would duplicate payment under other program authorities; and (3) the amendment would restrict beneficiary freedom of choice by limiting providers to employees of public welfare agencies.

Medicaid coverage of targeted case management is authorized by section 1915(g) of the Act, which defines case management as services that assist beneficiaries in gaining access to needed services and does not include the direct provision of those services. Because the services proposed as Medicaid targeted case management are segments of child welfare services related to the foster care program, CMS is of the belief that they are integral components of the direct services and administrative functions of child welfare services.

During conversations between CMS and the State of Maryland, the State cited section 8435 of the Technical and Miscellaneous Revenue Act of 1988, Pub. L. 100–647. In this section Congress clarified that the Secretary may not deny approval of either a SPA or a claim on the basis that the state is required to provide such services under state law, or is, or was otherwise paying for the services using non-Federal funds. However, section 8435 also expressly stated that this was not to be construed to require the Secretary to make payment for case management services that are provided without charge to the users of such services. Approval of SPA 02–05 would be contrary to this express statutory provision, since this SPA seeks payment from Medicaid program for services that are available without charge to the users.

In addition, while states are free to set qualifications for providers, a state must comply with Medicaid law and regulations concerning freedom of choice at section 1902(a)(23) of the Act and the implementing regulation at 42 CFR 431.51. These provisions require that a state plan permit beneficiaries to obtain services from any qualified provider that undertakes to provide the services. Section 1915(g)(1) of the Act states ''The provision of case management services under this subsection shall not restrict the choice of the individual to receive assistance in violation of section 1902(a)(23).''

Section 1116 of the Act and 42 CFR, part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. The CMS is required to publish a copy of the notice to a state Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants. Therefore, based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), CMS disapproved Maryland SPA (02–05).

The notice to Maryland announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Georges C. Benjamin, M.D.
Secretary, Department of Health and Mental Hygiene, 201 West Preston Street, Baltimore, MD 21201.

Dear Dr. Benjamin: I am responding to your request for reconsideration of the decision to disapprove Maryland State Plan Amendment (SPA) 02–05. This SPA was disapproved on August 26, 2002.

In this amendment, Maryland proposes to cover targeted case management services for abused and neglected children under foster care. At issue is whether the Centers for Medicare & Medicaid Services (CMS) properly concluded as a basis for disapproving the amendment that: (1) The State had not demonstrated that the proposed services were within the statutory definition of case management services found in section 1915(g)(2) of the Social Security Act (the Act); (2) the proposed services are available without charge to the user and thus payment under the amendment is not reasonable and necessary and would duplicate payment under other program authorities; and (3) the amendment would restrict beneficiary freedom of choice by limiting providers to employees of public welfare agencies.

Medicaid coverage of targeted case management is authorized by section 1915(g) of the Act, which defines case management as services that assist beneficiaries in gaining access to needed services and does not include the direct provision of those services. Because the services proposed as Medicaid targeted case management are segments of child welfare services related to the foster care program, CMS is of the belief that they are integral components of the direct services and administrative functions of child welfare services.

During conversations between CMS and the State of Maryland, the State cited section 8435 of the Technical and Miscellaneous Revenue Act of 1988, Pub. L. 100–647. In this section Congress clarified that the Secretary may not deny approval of either an SPA or a claim on the basis that the state is required to provide such services under state law, or is, or was otherwise paying for the services using non-Federal funds. However, section 8435 also expressly stated that this was not to be construed to require the Secretary to make payment for case management services that are provided without charge to the users of such services. Approval of SPA 02–05 would be contrary to this express statutory provision, since this SPA seeks payment from the Medicaid program for services that are available without charge to the users.

In addition, while states are free to set qualifications for providers, a state must comply with Medicaid law and regulations concerning freedom of choice at section 1902(a)(23) of the Act and the implementing regulations at 42 CFR 431.51. These provisions require that a state plan permit beneficiaries to obtain services from any qualified provider that undertakes to provide the services. Section 1915(g)(1) of the Act states ''The provision of case management services under this subsection shall not restrict the choice of the individual to receive assistance in violation of section 1902(a)(23).'' Therefore, based on the reasoning set forth above, and after consultation with the Secretary as required under 42 CFR 430.15(c)(2), CMS disapproved Maryland SPA 02–05.

I am scheduling a hearing on your request for reconsideration to be held on December 19, 2002, Suite 216, The Public Ledger Building, 150 S. Independence Mall West, Philadelphia, Pennsylvania 19106, at 10 a.m. to reconsider our decision to disapprove Maryland SPA 02–05.

If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,
Thomas A. Scully.

Sec. 1116 of the Social Security Act (42 U.S.C. section 1316); 42 CFR 430.18)

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

Dated: November 4, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–28469 Filed 11–7–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2912]

Final Guidance for Industry on the Development of Supplemental Applications for Approved New Animal Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#82) entitled ''Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs.'' This guidance explains how and when drug sponsors may use data collected for original new animal drug applications (NADAs) to support the technical sections of a supplemental NADA. The guidance also explains when the Center may, under existing statutes or regulations, require the submission of new data. Finally, the guidance delineates the instances in which a sponsor will generally need to file a new NADA rather than a supplemental application.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Marilyn N. Martinez, Office of New Animal Drug Evaluation (HFV–130), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7577, e-mail: *mmartine@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115) was signed into law. Section 403 of FDAMA requires FDA to provide information regarding approval of supplemental applications for approved products.

Section 403(b)(2) of FDAMA requires that FDA issue guidance on specific data requirements for supplemental NADAs in order to prevent duplication of previously submitted data. In the **Federal Register** of February 8, 2000 (65 FR 6214), FDA announced the availability of a draft guidance for industry entitled ''Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs.'' The draft guidance illustrated the various types of supplemental applications and their dependence on new data. This draft guidance explained how and when drug sponsors could use data accepted in support of an original application to support supplemental applications. The draft guidance also explained when a sponsor should submit a new NADA rather than a supplemental NADA. The agency received no comments on the draft guidance. The content of the final guidance is the same as the draft.

''Guidance for Industry: Development of Supplemental Applications for Approved New Animal Drugs'' demonstrates the agency's dedication to assisting the sponsor in creating a project development strategy and to fostering a discussion between the sponsor and the agency. With this in mind, the guidance is organized in a user-friendly format with two distinctive sections. The first section separates supplemental applications into two categories: Category I includes applications that do not ordinarily require additional data and category II includes applications that may require additional data. The guidance then lists the 14 types of supplemental applications in each category as well as the instances in which a sponsor generally will need to file a new NADA rather than a supplemental NADA.

The second section is dedicated to clarification of category II supplemental applications and the data to meet the technical section requirements. The data CVM would recommend be submitted for each category II supplement are provided in tables. The tables indicate if: (1) New data will generally be needed, (2) existing data included in a previously approved application will generally suffice, or (3) the nature of the supplemental application will dictate whether or not new data are generally needed. A comment section follows each table providing explanations and suggestions to the sponsor. The guidance also cross-references several FDA documents relating to the processing of supplemental applications, providing further assistance to the sponsor.

This final level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the development of supplemental applications for approved new animal drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this final guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The final guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cvm*.

Dated: October 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28472 Filed 11–7–02; 8:45 am]

BILLING CODE 4160–01–S