

HHAs and its survey process in ACHC's Surveyor Training Manual with the Medicare HHA conditions for participation and our State Operations Manual. Our review and evaluation of ACHC's deeming application, which were conducted as described in section III of this final notice yielded the following:

- To meet the full intent of all Medicare standards and conditions, ACHC crosswalked the corresponding Medicare standard to each of its standards and stated that HHAs undergoing a deemed status survey from ACHC would meet the ACHC standard as well as the corresponding Medicare standard.

- ACHC added time frames to respond to complaints in all categories listed in its complaint process.

- ACHC revised its survey procedures to add triggers for identification of Immediate Jeopardy and the guidelines to determine when Immediate Jeopardy is removed.

- ACHC amended its guidelines for determining survey frequency for HHAs in accordance with the State Operations Manual (SOM) 2195.

- In order to be consistent with our policy, ACHC modified the language in its policies to state that Branch Office Additions must first be approved by the CMS Regional Office before scheduling a survey.

- ACHC modified its policies to conform with our standards in SOM 2200 that HHAs applying for an initial certification survey provide care to at least 10 patients and that 7 of those 10 are still active at the time of the initial survey.

- To meet our standards listed in SOM 2200C4, ACHC amended its policies to include criteria necessary for the required number of home visits required during the survey.

- ACHC developed a systematic way to ensure that the appropriate number of active and closed records was reviewed for the size of the facility being surveyed in order to meet the standards listed at SOM 2200C5.

- ACHC established a new policy that requires all deemed HHAs to submit a Plan of Correction for all deficiencies identified.

- A new policy was developed by ACHC concerning the qualifications and training necessary for lead surveyors.

- ACHC will implement an annual training program for all its surveyors and incorporate a measurement tool that evaluates effectiveness of training.

- To meet the requirements listed in § 488.4(b)(3)(v), ACHC established a policy that permits its surveyors to serve

as witnesses if we take an adverse action based on accreditation findings.

- ACHC revised its policies to eliminate pre-survey contact and notification of surveyors to HHAs in order to meet our requirements of fully unannounced HHA surveys.

B. Term of Approval

Based on the review and observations described in section III of this final notice, we have determined that ACHC's requirements for HHAs meet or exceed our requirements. Therefore, we recognize the ACHC as a national accreditation organization for HHAs that request participation in the Medicare program, effective February 24, 2006 through February 24 2009.

V. Collection of Information Requirements

This final notice does not impose any information collection and record-keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA.

VI. Regulatory Impact Statement

We have examined the impact of this final notice as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 98–354). 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 for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary 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 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes ACHC as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is

not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by ACHC as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb) (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: January 30, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06–1650 Filed 2–23–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

Notice of Hearing: Reconsideration of Disapproval of Iowa State Plan Amendments 05–003

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing to be held on April 13, 2006, at the Richard Bolling Federal Building, 601 E. 12th Street, Room 235, Kansas City Conference Room, Kansas City, MO 64106–2898, to

reconsider CMS' decision to disapprove Iowa State plan amendment 05-003.

Closing Date: Requests to participate in the hearing as a party must be received by the presiding officer by March 13, 2006.

FOR FURTHER INFORMATION CONTACT:

Kathleen Scully-Hayes, Presiding Officer, CMS, Lord Baltimore Drive, Mail Stop LB-23-20, Baltimore, Maryland 21244, Telephone: (410) 786-2055.

SUPPLEMENTARY INFORMATION:

This notice announces an administrative hearing to reconsider CMS' decision to disapprove Iowa State plan amendment (SPA) 05-003 which was submitted on March 29, 2005. This SPA was disapproved on November 23, 2005. Under SPA 05-003, Iowa sought to simplify its State plan provisions on drug pricing, reflecting the implementation of State supplemental rebates and preferred drug list.

This amendment was disapproved because it did not comport with the requirements of the Federal regulations at 42 CFR 447.331(c) and sections 1902(a)(54) and 1927 of the Social Security Act (the Act) and implementing regulations.

Specifically, Iowa failed to demonstrate that SPA 05-003 is consistent with the Federal upper limit (FUL) regulations at 42 CFR 447.331(c). This regulation provides that the upper limit for payment for multiple source drugs for which a specific limit has been established does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary. The State asserted that the physician certification provision (regarding the medical necessity of a brand name drug) need not be followed as part of the State's drug reimbursement methodology because the net cost, after rebates, of these brand name drugs will not exceed the FUL. The State, however, failed to demonstrate how this assertion is consistent with the plain language of the regulation which provides for an FUL based on State payment rates for prescription drugs (without regard to manufacturer rebates), and an FUL exemption based on physician certification.

The State also failed to demonstrate compliance with sections 1902(a)(54) and 1927 of the Act, which provide for the calculation of rebates for covered outpatient drugs, based on payment that was made under the State plan. Section 1927(b)(1)(B) of the Act provides for an offset against medical assistance to account for such rebates. Such an offset would not be necessary if the reference

to "payment" was intended to be a net payment and include rebates that are eventually provided under section 1927. The State did not demonstrate that its methodology is consistent with sections 1902(a)(54) and 1927 of the Act which are not intended to change State payment rates for prescription drugs and which, as noted previously, provide for calculation of rebates based on State payment.

For the reasons cited above, and after consultation with the Secretary, as required by the Federal regulations at 42 CFR section 430.15(c)(2), Iowa SPA 05-003 was disapproved.

Section 1116 of the Act and Federal regulations at 42 CFR Part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. 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.

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

Mr. Daniel W. Hart, Assistant Attorney General, Counsel to the Iowa Department of Human Services, Regents and Human Services Division, 1305 E. Walnut Street, Des Moines, IA 50319-0109.

Dear Mr. Hart:

I am responding to your request for reconsideration of the decision to disapprove the Iowa State plan amendment (SPA) 05-003, which was submitted on March 29, 2005, and disapproved on November 23, 2005.

Under SPA 05-003, Iowa was seeking to simplify its State plan provisions on drug pricing, reflecting the implementation of State supplemental rebates and the preferred drug list.

This amendment was disapproved because it did not comport with the requirements of the Federal regulations at 42 CFR 447.331(c) and sections 1902(a)(54) and 1927 of the

Social Security Act (the Act) and implementing regulations.

Specifically, Iowa failed to demonstrate that SPA 05-003 is consistent with the Federal upper limit (FUL) regulations at 42 CFR 447.331(c). This regulation provides that the upper limit for payment for multiple source drugs for which a specific limit has been established does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary. The State asserted that the physician certification provision (regarding the medical necessity of a brand name drug) need not be followed as part of the State's drug reimbursement methodology because the net cost, after rebates, of these brand name drugs will not exceed the FUL. The State, however, failed to demonstrate how this assertion is consistent with the plain language of the regulation which provides for an FUL based on State payment rates for prescription drugs (without regard to manufacturer rebates), and an FUL exemption based on physician certification.

The State also failed to demonstrate compliance with sections 1902(a)(54) and 1927 of the Act, which provide for the calculation of rebates for covered outpatient drugs, based on payment that was made under the State plan. Section 1927(b)(1)(B) of the Act provides for an offset against medical assistance to account for such rebates. Such an offset would not be necessary if the reference to "payment" was intended to be a net payment and include rebates that are eventually provided under section 1927. The State did not demonstrate that its methodology is consistent with sections 1902(a)(54) and 1927 of the Act which are not intended to change State payment rates for prescription drugs and which, as noted previously, provide for calculation of rebates based on State payment.

For the reasons cited above, and after consultation with the Secretary, as required by 42 CFR 430.15(c)(2), Iowa 05-003 was disapproved.

I am scheduling a hearing on your request for reconsideration to be held on April 13, 2006, at the Richard Bolling Federal Building, 601 E. 12th Street, Room 235, Kansas City Conference Room, Kansas City, MO 64106-2898, to reconsider the decision to disapprove SPA 05-003. 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 at (410) 786-2055. 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.

Sincerely,
Mark B. McClellan, M.D., Ph.D.

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

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

Dated: February 13, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06-1647 Filed 2-23-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Temporary Assistance for Needy Families (TANF/National Directory of New Hires (NDNH) Match Results Report.

OMB No.: New Collection.

Description: Section 453(j)(3) of the Social Security Act (the Act) allows for matching between NDNH (maintained by the Federal Office of Child Support Enforcement (OCSE) and State TANF

agencies for the purpose of carrying out responsibilities under programs funded under part A of Title IV of the Act. To assist OCSE and the Office of Family Assistance in measuring savings to the TANF program of Family Assistance in measuring savings to the TANF program attributable to the use of NDNH data matches, the State TANF agencies have agreed to provide OCSE with a written description of the performance outputs and outcomes attributable to the State TANF agencies' use of NDNH match results. This information will help OCSE demonstrate how the NDNH supports the President's Management Agenda as well as OCSE's mission and strategic goals.

Respondents: State TANF Agencies.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--------------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| TANF/NDNH Match Results Report | 40 | 4 | .17 | 27 |

Estimated Total Annual Burden Hours: 27

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 16, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06-1699 Filed 2-23-06; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Annual Aggregate Report.

OMB No.: 0970-0150.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101-508, 42 U.S.C. 9858) requires that the States and the Territories submit annual aggregate data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Annual aggregate reports include data elements represented in the ACF-800. The Administration for Children and Families (ACF) uses aggregate data to determine the scope, type, and methods of child care delivery. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF-800.

Respondents: States, the District of Columbia, and the Territories, including Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| ACF-800 | 56 | 1 | 40 | 2,240 |