

along with a claim for reimbursement. *Form Number:* CMS-484 (OMB control number: 0938-0534); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-profits); *Number of Respondents:* 8,880; *Total Annual Responses:* 1,632,000; *Total Annual Hours:* 326,500; (For policy questions regarding this collection contact Paula Smith at 410-786-4709.)

2. Type of Information Collection
Request: Revision of a currently approved collection; *Title of Information Collection:* Durable Medical Equipment Medicare Administrative Contractors (MAC) Regional Carrier, Certificate of Medical Necessity and Supporting Documentation; *Use:* The certificates of medical necessity (CMNs) collect information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant, LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN (paper or electronic) to CMS, along with a claim for reimbursement. *Form Number:* CMS-846-849, 854, 10125 and 10126 (OMB control number: 0938-0679); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-profits); *Number of Respondents:* 462,000; *Total Annual Responses:* 462,000; *Total Annual Hours:* 418,563; (For policy questions regarding this collection contact Paula Smith at 410-786-4709.)

3. Type of Information Collection
Request: Extension of a previously approved collection; *Title:* Data Collection for Medicare Beneficiaries Receiving NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; *Use:* In Decision Memorandum #CAG-00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is

sufficient to conclude that for Medicare beneficiaries receiving NaF-18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to information at the time of the scan to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meets specified standards and address the specified research questions. To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. The statutory authority for this policy is section 1862 (a)(1)(E) of the Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. *Form Number:* CMS-10152 (OCN: 0938-0968); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits); *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 2,084 hours. (For policy questions regarding this collection contact Stuart Caplan at 410-786-8564.)

Dated: May 6, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

New Funding Formula

AGENCIES: Administration on Intellectual and Developmental

Disabilities (AIDD), Administration on Disabilities (AoD), Administration for Community Living (ACL), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Administration on Intellectual and Developmental Disabilities (AIDD) within the Administration on Disabilities (AoD), located within the Administration for Community Living (ACL) at the United States Department of Health and Human Services (HHS), has developed a new funding formula for the State Councils on Developmental Disabilities (SCDD) and Protection and Advocacy Systems (P&A) located in each State and Territory.

DATES: Effective Date October 1, 2016.

ADDRESSES: The new formula is printed below and the estimated allotments for FY 2017 for each SCDD and P&A can be found at: http://www.acl.gov/About_ACL/Allocations/DD-Act.aspx.

FOR FURTHER INFORMATION CONTACT:

Andrew Morris, Office of the Commissioner, Administration on Disabilities, 330 C St. SW., Washington, DC 20201. Telephone (202) 795-7408. Email andrew.morris@acl.hhs.gov.

Please note the telephone number is not toll free. This document will be made available in alternative formats upon request. Written correspondence can be sent to Administration for Community Living, U.S. Department of Health and Human Services, 330 C St. SW., Washington, DC 20201.

SUPPLEMENTARY INFORMATION:

Background

The Developmental Disabilities Assistance and Bill of Rights Act of 2000 (Pub. L. 106-402) provides, among other things, formula grants to States for the purpose of operating State Councils on Developmental Disabilities and Protection & Advocacy Systems for people with developmental disabilities. The Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) provides authority and flexibility in Section 122 to determine the formula for distributing the annual grant awards as long as the three statutory factors are met. These factors are:

1. Total population of the State/Territory
 2. Need for services for people with developmental disabilities in the State/Territory
 3. Financial need of the State/Territory
- Responding to years of requests for a modernized funding formula and after a

comprehensive development process, AIDD published a notice in the **Federal Register** on February 18, 2016 seeking comments on a new funding formula (81 FR 8204). AIDD has reviewed the comments submitted and is moving forward with the proposed formula. AIDD believes that this formula is clear, concise, transparent, and consistent with Congress' intent to provide funds to States based on greatest need. For the P&A program, in response to the comments received, AIDD will adopt this new formula over a three year period.

For complete details on methodology and development of the new formula please see the **Federal Register**, February 18, 2016, Vol 81, Number 32, Pages 8204–8205.

New Formula

Beginning in FY 2017, AIDD will use a new formula to distribute funds to SCDD and P&A programs after meeting statutory minimums and hold-harmless requirements for the SCDD. Funding will be allocated to States and Territories based on the following criteria:

1. *State/Territory Population (30%)*: Based on July Census figures released in August of each year.

2. *Need for services (30%)*: Based on a 1.58 percent prevalence rate for developmental disabilities in each State and Territory from the HHS National Health Interview Survey on Disability (NHIS–D).

3. *Financial need (40%)*: Based on a combination of poverty (20%) and seasonally adjusted unemployment rates (20%) from July of each calendar year.

New Formula Phase-In

In their comments to AIDD, numerous P&A programs requested to phase in the new formula as a way of offsetting losses some grantees would experience if AIDD were to begin using the new formula immediately in FY 2017. AIDD concurs with this requested approach, and the new formula will be phased in for the P&A programs only with funds allotted in the following manner:

FY 2017: 75 percent previous formula and 25 percent new formula

FY 2018: 50 percent previous formula and 50 percent new formula

FY 2019: 100 percent new formula

The new formula will be in full effect for the SCDD programs on October 1, 2016. SCDDs will likely not experience significant fluctuations in their annual allotment due to that program's hold-harmless requirement.

Response to Public Comments

General

AIDD received 75 comments related to the new formula including 39 comments from SCDDs and 18 from P&As. AIDD also received 18 comments from other entities including non-profits and State agencies. Comments were received on each of the three required formula factors and weighting of the factors. Comments on the new formula were generally favorable and supportive. Commenters acknowledged that the current formula is more than 35 years old and uses data sources that do not adequately take into account the needs of people with developmental disabilities. Generally, they found the new formula to be more transparent and easier to understand. Comments also reinforced the need for the new formula in order to ease the administrative burden on ACL. Commenters pointed out that the previous formula used the per capita income rate which was an inadequate way to measure financial need and AIDD concurs with this comment. Several commenters stated that the current minimum allotments are inadequate; however these minimum allotments are set in statute and therefore not subject to change by AIDD.

Population

Some commenters requested that population have a higher weight in the formula. AIDD declined to raise the weighting as doing so could cause larger swings in the formula year-to-year and thereby make it more difficult for States to plan for their operating needs. Some commenters asked for the population of people with developmental disabilities to be considered rather than the total population. However, the DD Act requires that the entire State population must be taken into consideration.

Need for Services

As the formula workgroup and AIDD determined, the most clear and concise way to determine the need for services was to use the most current federal data for prevalence of people with developmental disabilities. Some commenters asked that AIDD use the Centers for Disease Control (CDC) prevalence rates for people with developmental disabilities, however, CDC's definition of developmental disabilities does not match AIDD's statutory definition.

Several commenters asked for different data to be used to determine the need for services in each State and Territory. There were varied opinions and suggestions, but none were clearly

stronger than the sources proposed by AIDD.

Commenters also asked for the use of prevalence rates by State. That data is not currently available. AIDD is working with its federal partners to identify future opportunities to better understand the prevalence of developmental disabilities.

Financial Need

AIDD and the formula workgroup weighted financial need at 40 percent, with 20 percent based on State/Territory poverty levels and 20 percent based on seasonally adjusted unemployment data from July of each year. The workgroup felt that these measures were the best economic indicators to measure a State's financial need.

Several commenters asked for additional measures such as cost of living adjustments, workforce participation rates, and supplemental measures of poverty. HHS data experts stated that these data were not as reliable as the ones proposed and that the use of any of these data, including workforce participation rates, would not make a significant difference in the distribution of funds. Further, use of several of the proposed data would make the formula more complicated. Other commenters stated the need to use different data sources but did not give alternatives as was requested in the request for public comments. Therefore, AIDD concluded that there was no compelling reason to change data used for financial need.

Dated: May 5, 2016.

Jennifer Johnson,

Deputy Director, Administration on Intellectual and Developmental Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0730]

Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.