

Sincerely,
Thomas A. Scully.

(Sect. 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: May 12, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

State Grants for Election Assistance for Individuals With Disabilities (EAID)

AGENCY: Administration on Developmental Disabilities (ADD), Administration for Children and Families, Department of Health and Human Services.

ACTION: Notification of the Availability of Fiscal Year 2003 Funds under the Help America Vote Act, Public Law (Pub. L.) 107-252, title II subtitle D, part 2, section 261, Payments to States and Units of Local Governments to Assure Access for Individuals with Disabilities (42 U.S.C. 15421).

SUMMARY: The purposes of this notice are: (1) To set forth the requirements that must be met by a State seeking a payment under 42 U.S.C. 15421 of the Help America Vote Act of 2002 (HAVA); and (2) to secure assurances from such a State related to conditions prior to receiving a payment.

EFFECTIVE DATE: May 21, 2003.

FOR FURTHER INFORMATION CONTACT: Contact Diann Winford at (202) 690-5963, dwinford@acf.hhs.gov or Carla Brown at (202) 690-8332, crbrown@acf.hhs.gov.

SUPPLEMENTARY INFORMATION:

Part I: Introduction

The Help America Vote Act (HAVA), signed into law by President George W. Bush on October 29, 2002, contains several provisions that will enable an applicant to establish, expand, and improve access to and participation by individuals with the full range of disabilities (e.g., blindness or visual impairment, deafness or hearing impairment, mobility-related, dexterity-related, emotional or intellectual) in the election process. The Catalog of Federal Domestic Assistance Number for this announcement is: 93.617.

Background

On February 20, 2003, in Division (N)—“Emergency Relief and Offsets,” Title I Election Reform, Disabled Voters Services, the Miscellaneous Appropriations Act, 2003, Pub. L. 108-7, Congress appropriated \$13 million for States to operate the Election Assistance for Individuals with Disabilities (EAID) grant program. HAVA assigned responsibility for the EAID to the Secretary of Health and Human Services (the Secretary), who has assigned responsibility for carrying out this program to the Administration for Children and Families (ACF). Within ACF, the Administration on Developmental Disabilities (ADD) is responsible for the administration of the EAID grant program.

Eligible Applicants

As defined by section 901 of HAVA, States (including the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, and the Virgin Islands) are eligible to apply for grants under the EAID program. Grants are not available to local units of government directly from the Federal Government in FY 2003 because Division (N)—“Emergency Relief and Offsets,” Title I Election Reform, Disabled Voters Services, the Miscellaneous Appropriations Act, 2003, Pub. L. 108-7, only appropriated funds for grants to States for FY 2003. Thus, while units of local government as well as States are eligible for funding under Section 261 of the Help America Vote Act, the annual appropriations statute did not make funds available for grants to local governments.

Availability and Distribution of Funds

Congress appropriated \$13,000,000 for payments to States for Federal fiscal year 2003. Payment amounts to States and Territories will be based on the relative size of the voting age population (i.e., number of individuals 18 years of age or older as reported in the 2000 U.S. Census) of those States and Territories requesting payment, with the exception that no State or Territory applying for funds shall receive a payment of less than \$100,000. See Table I for the amount reserved for each State and Territory, assuming all 55 States and Territories submit applications. If fewer than 55 States and Territories submit applications, those States and Territories applying for payment will receive a proportionately higher amount than that listed on Table I.

Any payment distributed shall remain available until expended.

In order to receive a payment a State must meet all of the requirements in

Part II of this Notice. State governments receiving funds under this announcement will need to collaborate with local chief election officials and local units of government to determine where and how to expend funds.

The Federal Government reserves the right to audit expenditure of funds received under this announcement pursuant to section 902 of the Help America Vote Act, 42 U.S.C. 15542 and 45 CFR 92.26, where applicable.

Use of Allotments

Section 261 of HAVA provides that funds be made available to:

a. Make polling places, including the path of travel, entrances, exits, and voting areas of each polling facility, accessible to individuals with the full range of disabilities (e.g., blindness or visual impairment, deafness or hearing impairment, mobility-related, dexterity-related, emotional, or intellectual).

b. Provide the same opportunity for access and participation (including privacy and independence) to individuals with the full range of disabilities.

c. Train election officials, poll workers, and election volunteers on how best to promote the access and participation of individuals with the full range of disabilities in elections for Federal office.

d. Provide individuals with the full range of disabilities with information about the accessibility of polling places.

Part II: Application Requirements

All of the following conditions must be met by an applicant seeking a payment under 42 U.S.C. 15421 of the Help America Vote Act of 2002. An applicant must agree to these conditions in writing prior to receiving a payment by submitting an application. The conditions are to ensure that a payment will be used in compliance with HAVA. Payments must be used to pay for the activities described under Part I, Use of Allotments.

Conditions

1. Some portion of the grant must be used for each of the following activities.

a. Make polling places, including the path of travel, entrances, exits, and voting areas of each polling facility, accessible to individuals with the full range of disabilities.

b. Provide the same opportunity for access and participation (including privacy and independence) to individuals with the full range of disabilities as for other voters.

c. Train election officials, poll workers, and election volunteers on how best to promote the access and

participation of individuals with the full range of disabilities in elections for Federal office.

d. Provide individuals with the full range of disabilities with information about the accessibility of polling places.

2. In an application an applicant must provide:

a. The name of the State submitting the application.

b. The name of the Chief Election Official of the State submitting the application.

c. Contact person: name, title, address, phone, fax, and e-mail address.

d. A description of what the applicant intends to do in *each* of the four categories of activities outlined under #1 above.

e. How much of the payment that the applicant intends to spend on each of the four categories of activities outlined in #1 above.

f. An assurance that six months after the ending of the fiscal year in which a payment is received, the Chief Election Official or his/her designee will submit a report to the Administration on Developmental Disabilities for the Secretary of Health and Human Services describing how the payment received was used with regard to the four categories of activities.

3. The application must include a completed SF 424, available at this Web address: <http://www.acf.hhs.gov/programs/add/announce.htm>

4. The application must include the following certifications:

a. Anti-Lobbying Certification and Disclosure Form (45 CFR part 93).

b. Other Certifications: The signature on the application by the authorized official attests to the intent to comply with the following other certifications:

A. Certification Regarding Drug-Free Work Place (45 CFR part 76)

B. Debarment Certification (45 CFR 76); and

C. Certification Regarding Environmental Tobacco Smoke.

5. The application must be signed by the Chief Election Official.

6. An application must be received 45 days from date of this notice, and no later than 4:30 p.m. EDT, at the U.S. Department of Health and Human Services, ACF/Office of Grants Management, 370 L'Enfant Promenade SW, Mail Stop 326F, Washington, DC 20447-0002, Attention: Joseph Lonergan. Hand-delivered applications should be delivered to Joseph Lonergan, Director, Division of Mandatory Grants, Office of Grants Management, 901 D Street, SW., 4th Floor East, Washington, DC (Telephone number: (202) 401-6603)). Any applications received after 4:30 p.m. on the deadline date will not be considered for payment.

Part III: Additional Information

Closing Date for Receipt of Assurances

The closing date for receipt of all applications is 45 days from the date of this notice.

Grant Administration Regulations

The regulations that govern the administration of these grants are: 45 CFR part 16—Procedures of the Departmental Grant Appeals Board; 45 CFR part 30—Claims Collection; 45 CFR part 76—Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants); 45 CFR part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services Effectuation of Title VI of the Civil Rights Act of 1964; 45 CFR part 81—Practice and Procedure for Hearings Under Part 80 of This Title; 45 CFR part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance; 45 CFR part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance; 45 CFR part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments; and 45 CFR part 93—New Restrictions on Lobbying.

Reporting Requirements

Each grantee is required to submit annually a narrative report that describes how the funds are used in regard to the four categories of activities authorized under 42 U.S.C. 15461 of the Help America Vote Act of 2002. These reports are due no later than March 31 of each year. Reports must be mailed to: Administration on Developmental Disabilities, 200 Independence Avenue, Southwest, Room 300-F, Washington, DC 20201, Attention: Debbie Powell.

Expenditures under the EAID program are to be reported using a Financial Status Report (SF-269A). Grantees are required to submit annual financial reports (SF-269A) at the end of each 12 month grant period (September 1–August 31) until all funds have been expended. Funds under EAID are available until expended. Reports are due 90 days after the end of the grant period (November 30).

Submit the original SF-269A to ACF at the address below:

Administration for Children and Families, Office of Administration, Division of Mandatory Grants, Attn: Joseph Lonergan, 370 L'Enfant

Promenade, SW, Washington, DC 20447.

Notification Under Executive Order 12372

This program is covered under E.O. 12372, "Intergovernmental Review of Federal Programs" and 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." However, since units of local governments are not funded in Fiscal Year 2003, the review and comment provisions of the Executive Order and Part 100 do not apply for fiscal year 2003.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96-511), the application requirements contained in this notice have been approved by the Office of Management and Budget under control number 0348-0043.

FY 2003 TENTATIVE ALLOCATIONS FOR ELECTION ASSISTANCE FOR INDIVIDUALS WITH DISABILITIES.—TABLE I

State	FY 2003 tentative allotments
Alabama	185,341
Alaska	100,000
American Samoa	100,000
Arizona	209,686
Arkansas	109,029
California	1,371,756
Colorado	178,308
Connecticut	142,841
Delaware	100,000
District of Columbia	100,000
Florida	687,278
Georgia	335,237
Guam	100,000
Hawaii	100,000
Idaho	100,000
Illinois	511,102
Indiana	251,048
Iowa	122,161
Kansas	110,057
Kentucky	169,755
Louisiana	181,021
Maine	100,000
Maryland	219,527
Massachusetts	270,154
Michigan	409,083
Minnesota	202,382
Mississippi	115,296
Missouri	232,185
Montana	100,000
Nebraska	100,000
Nevada	100,000
New Hampshire	100,000
New Jersey	352,485
New Mexico	100,000
New York	795,936
North Carolina	339,029
North Dakota	100,000
Oregon	143,454
Pennsylvania	521,409

FY 2003 TENTATIVE ALLOCATIONS FOR
ELECTION ASSISTANCE FOR INDIVID-
UALS WITH DISABILITIES.—TABLE I—
Continued

State	FY 2003 tentative allotments
Puerto Rico	151,345
Rhode Island	100,000
South Carolina	167,271
South Dakota	100,000
Tennessee	240,958
Texas	833,749
Utah	100,000
Vermont	100,000
Virgin Islands	100,000
Virginia	297,522
Washington	244,039
West Virginia	100,000
Wisconsin	185,426
Wyoming	100,000
Total	13,000,000

Dated: May 14, 2003.

Patricia A. Morrissey,
*Commissioner, Administration on
Developmental Disabilities.*

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. 03N-0038]

**Agency Information Collection
Activities; Submission for OMB
Review; Comment Request; Medical
Device User Fee Cover Sheet; Form
FDA 3601**

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.

DATES: Submit written or electronic
comments on the collection of
information by June 20, 2003.

ADDRESSES: The Office of Management
and Budget (OMB) is still experiencing
significant delays in the regular mail,
including first class and express mail,
and messenger deliveries are not being
accepted. To ensure that comments on
the information collection are received,
OMB recommends that written
comments be electronically mailed to
sshapiro@omb.eop.gov or faxed to the
Office of Information and Regulatory
Affairs, OMB, Attn: Stuart Shapiro, Desk
Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT:
Peggy Robbins, Office of Information
Resources Management (HFA-250),
Food and Drug Administration, 5600
Fishers Lane, Rockville, MD 20857,
301-827-1223.

SUPPLEMENTARY INFORMATION: In
compliance with 44 U.S.C. 3507, FDA
has submitted the following proposed
collection of information to OMB for
review and clearance.

**Medical Device User Fee Cover Sheet;
Form FDA 3601**

The Federal Food, Drug, and Cosmetic
Act, as amended by the Medical Device
User Fee and Modernization Act of 2002
(MDUFMA) (Public Law 107-250),
authorizes FDA to collect user fees for
certain medical device applications.
Under this authority, companies pay a
fee for certain new medical device
applications or supplements submitted
to the agency for review. Because the
submission of user fees concurrently
with applications and supplements is
required, the review of an application
cannot begin until the fee is submitted.
Form FDA 3601, the "Medical Device
User Fee Cover Sheet," is designed to
provide the minimum necessary
information to: (1) Determine whether a
fee is required for review of an

application, (2) determine the amount of
the fee required, and (3) account for and
track user fees. The form provides a
cross-reference of the fees submitted for
an application with the actual
application by using a unique number
tracking system. The information
collected is used by FDA's Center for
Devices and Radiological Health (CDRH)
and Center for Biologics Evaluation and
Research (CBER) to initiate the
administrative screening of new medical
device applications and supplemental
applications.

Respondents to this collection of
information are device manufacturers.
Based on FDA's database system, there
are an estimated 5,000 manufacturers of
products subject to MDUFMA.
However, not all manufacturers will
have any submissions in a given year
and some may have multiple
submissions. The total number of
annual responses is based on the
number of submissions received by FDA
in fiscal year 2002. CDRH estimates
5,000 annual responses that include the
following: 50 premarket approval
applications, 4,400 premarket
notifications, 30 modular premarket
applications, 1 product development
protocol, 1 premarket report, 20 panel
track supplements, 150 real-time
supplements, and 348 180-day
supplements. CBER estimates 50 annual
responses that include the following: 2
premarket approval applications, 3
biologics license applications, 30
premarket notifications, 10 modular
premarket applications, and 5 180-day
supplements. The estimated hours per
response are based on past FDA
experience with the various
submissions, and range from 5 to 30
minutes. The hours per response are
based on the average of these estimates.

In the **Federal Register** of February
26, 2003 (68 FR 8907) FDA published a
60-day notice requesting public
comment on the information collection
provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3601	5,000	1	5,000	.30	1,500

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.