

Medicare Beneficiaries, due to provider non-payment.

HCFA is requesting that OMB provide a seven working day review and a 180-day approval. During this 180-day period HCFA will pursue OMB clearance of this collection as stipulated by 5 CFR 1320.5.

**1. Type of Information Collection**

**Request:** Reinstatement without change, of a previously approved collection;  
**Title of Information Collection:** Medicare/Medicaid Health Insurance Common Claim Form and Instructions, and Supporting Regulations 42 CFR 424.32 (Basic Requirements for all Claims) and 42 CFR 414.40 (Coding and Ancillary Policies); **Form No.:** HCFA-1500; **Use:** This form and instructions are standardized for use in the Medicare/Medicaid programs to apply for reimbursement for covered services. HCFA does not require exclusive use of this form for Medicaid. 42 CFR 424.32 and 42 CFR 414.40 are regulations underlying the use of the form HCFA-1500 and the information captured on the form HCFA-1500, including the use of diagnostic and procedural coding systems; **Frequency:** On occasion; **Affected Public:** Business or other for profit, not for profit institutions, State, local or tribal government; **Number of Respondents:** 976,239; **Total Annual Responses:** 614,967,982; **Total Annual Hours:** 52,139,385.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1325. Written comments and recommendations for the proposed information collections should be sent within five working days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC. 20503.

Dated: January 23, 1997.

Edwin J. Glatzel,

*Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.*

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[ORD-089-N]

**Medicare and Medicaid Programs;  
Small Business Innovation Research  
Grants for Fiscal Year 1997**

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of HCFA funding, through grants, for small businesses under the Small Business Innovation Research (SBIR) Program. This notice contains information about the subject areas for grants that will be given priority, application requirements, review procedures, and other relevant information.

**DATES:** Grant applications must be submitted by April 29, 1997, in order to be considered under the fiscal year (FY) 1997 annual funding cycle.

**ADDRESSES:** Standard application forms and related instructions are available from and must be formally submitted to: HCFA Grants Officer, Office of Acquisition and Grants, Health Care Financing Administration, 7500 Security Boulevard, C2-21-15, Baltimore, MD 21244-1856, (410) 786-5701.

**FOR FURTHER INFORMATION CONTACT:** Carl Hackerman, (410) 786-6644. *Internet:* Chackerman@hcfa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Small Business Innovation Research Program**

The Small Business Innovation Development Act of 1982 (Public Law 97-219, enacted on July 22, 1982), as amended by the Small Business Innovation Research Program Extension (Public Law 99-443, enacted on October 6, 1986), the Small Business Administration Reauthorization and Amendment Act of 1988 (Public Law 100-590, enacted on November 3, 1988), the Small Business Research and Development Enhancement Act of 1992 (Public Law 102-564, enacted on October 28, 1992), and the Small Business Administration Reauthorization Act of 1994 (Public Law 104-403, enacted on October 2, 1994), (15 U.S.C. 638(e) through (m)), requires Federal agencies to reserve a specific amount of their extramural research and budgets for a Small Business Innovation Research (SBIR) Program. This SBIR Program is intended to—

- Stimulate technological innovation;
- Use small business to meet Federal research and demonstrations ("R & D") needs;
- Increase private sector commercialization of innovations derived from Federal R & D; and
- Foster and encourage participation by minority and disadvantaged persons in technological innovation.

The principal purpose of HCFA's SBIR Program is to provide assistance to creative applicants so that innovation

can be encouraged that will result in better health care.

**A. SBIR Program Phases, Award Amounts, and Period of Support**

The SBIR Program consists of the following three phases:

**Phase I**

The objective of this phase is to establish the technical merit and feasibility of proposed research or Research and Demonstrations efforts and to determine the quality of performance of the small business awardee organization before furnishing further Federal support in Phase II. Phase I awards will be approximately \$50,000 (for both direct and indirect costs) for a period not to exceed 12 months.

**Phase II**

The objective of this phase is to continue the research or R & D efforts initiated in Phase I and to actually create the proposed product and test it before marketing. Funding is based on the results of Phase I and technical merit of the Phase II application, including its potential for commercialization. (Only Phase I awardees are eligible to apply for Phase II funding.) Phase I awardees are eligible to apply for Phase II funding only from the Federal agency that supported their Phase I project. Phase II awards will be approximately \$100,000 to 150,000 (for both direct and indirect costs) for a period normally not to exceed 12 months.

**Phase III**

The objective of this phase, if appropriate, is for the small business concern to pursue with non-Federal funds the commercialization of the results of the research or R & D in Phases I and II.

The purpose of this notice is to invite Phase I and II grant applications from for-profit domestic small business concerns that have the expertise to develop or further develop innovative technology. This technology should be compatible with the general mission of HCFA and contribute to the health care field. HCFA is responsible for the Medicare program, Federal participation in the Medicaid program, and related health care quality assurance programs. HCFA's mission is to promote the timely delivery of appropriate quality health care to its Medicare beneficiaries and Medicaid recipients—over 70 million of the nation's aged, disabled, and poor. HCFA must also ensure that Medicare beneficiaries and Medicaid recipients are aware of the services for

which they are eligible. In addition, HCFA must ensure that those services are accessible and of high quality.

In carrying out its mission, HCFA conducts studies and projects that examine and demonstrate payment, coverage, eligibility, and management alternatives to the present programs. HCFA also studies the impact of HCFA programs on health care costs, program expenditures, beneficiary and recipient access to services, health care providers, and the health care segment of the American economy.

In addition, HCFA monitors national health care expenditures and prices and provides analyses of the costs of current programs, as well as the impact of possible legislative or administrative changes in the programs. HCFA's Office of Research and Demonstrations (ORD) is responsible for the technical aspects of the SBIR Program described in this section.

This notice outlines the eligibility requirements for organizations wishing to participate in the HCFA SBIR Program and the research grant application and review processes. It also provides both general program information as well as specific research topics and subtopics that may be of interest to small business concerns.

Although areas of special programmatic interest or priority are described in section VII. of this notice, we will consider grant applications in any area within the field of health care research and demonstrations unless otherwise specifically excluded. However, we are not generally interested in funding the biomedical or clinical projects that more appropriately fit the mission of the National Institutes of Health.

### *B. Eligibility*

Each organization submitting a grant application under our SBIR Program must qualify as a small business concern. "Small business concern" is defined in section II.F. of this notice. In determining whether an applicant is a small business concern, an assessment will be made of several factors, including whether it is organized for profit, whether it is independently owned and operated, and whether it meets the size requirement of 500 or fewer employees. Whether the size requirement is met may depend on whether the applicant organization is affiliated with another organization whose employees, when added to those of the applicant organization, exceed 500. In conducting this assessment, all appropriate factors will be considered, including common ownership, common

management, and contractual relationships.

Affiliation exists when one concern controls or has the power to control the other, or there is third party control, or an identity of interest between or among parties exists so that affiliation may be found. Control may be affirmative or negative, and it is immaterial whether it is exercised so long as the power to control exists. Indeed, control can arise from a variety of circumstances. One example of a circumstance that could lead to a finding that an organization is controlling, or has the power to control, another organization is the sharing of common office space, employees, or other facilities (for example, laboratory space). Although access to special facilities or equipment in another organization is permitted (as in cases in which the SBIR applicant has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project), research space occupied by an SBIR applicant must be space that is not generally shared with another organization and over which the applicant has exclusive control. When there is an indication of sharing of common employees, a determination will be made on a case-by-case basis of whether the sharing constitutes control or the power to control.

Additionally, control or the power to control is generally considered to exist when "key employees of one concern organize a new concern and serve as its officers, directors, principal stockholders, and/or key employees, and the one concern is furnishing or will furnish the other concern with subcontracting financial or technical assistance, bid or performance bond indemnification, and/or other facilities, whether for a fee or otherwise." Affiliation can also arise between or among two or more persons when an identity of interest exists, such as members of the same family or persons with common investments in more than one concern.

All SBIR grant applications will be reviewed with the above considerations in mind. Organizations considering submitting an application are referred to the SBA's SBIR Program Policy Directive published in the Federal Register on January 26, 1993 (58 FR 6144) and to the regulations set forth at 13 CFR part 121 for further guidance regarding eligibility. In particular, to determine whether affiliation exists, the applicant should also refer to 13 CFR 121.401 for the definition of affiliation, which will be used as HCFA's guide on this matter. If it appears that an applicant organization does not meet

eligibility requirements with respect to size, HCFA will request a size determination of the organization from the applicable Small Business Administration (SBA) regional office. The review of the application may be deferred until a definitive response is furnished by SBA.

Of particular concern in considering grant awards is the position of principal investigator. We wish to ensure that support is furnished to a carefully directed working group led by an individual personally committed to the development of the innovation. Accordingly, we are adopting the "principal investigator" concept from 42 CFR part 52. These regulations define the term "principal investigator" to mean "a single individual designated by the grantee in the grant application \* \* \* who is responsible for the scientific and technical direction of the project" (42 CFR 52.2). In order to meet this standard, the principal investigator's primary employment must be with the grantee at the time of the award and remain so for the duration of the project. Primary employment means that more than one-half of the principal investigator's time is spent in the employment of the small business concern. Primary employment with a small business concern precludes full-time employment at another organization.

In accordance with SBA's SBIR Program Policy Directive published in the Federal Register on January 26, 1993 (58 FR 6144), we have further restricted the definition of primary employment of the principal investigator to accurately reflect HCFA's needs. The applicant must declare the principal investigator's employment, whether paid or unpaid, at the time of application, and must declare all employment relationships, whether paid or unpaid, that the principal investigator is expected to have at the time the SBIR grant awards are expected to be made and for the duration of the proposed project. In the event that, at the time of application, the principal investigator (1) is, or expects to be, a less-than-full-time employee of the small business concern; (2) is, or expects to be, concurrently employed by another organization; or (3) gives, or expects that he or she may give, the appearance of being concurrently employed by another organization, whether for a paid or unpaid position, it is essential that documentation be submitted with the application to verify the applicant's eligibility at the time of the award. Thus, if the principal investigator is also employed or appears to be employed by an institution other

than the applicant organization (for example, a university, nonprofit research institute, or a company other than the applicant organization), a letter must be furnished by the nonapplicant organization confirming that the principal investigator, if awarded an SBIR grant, is, or will become, a less-than-half-time employee of the organization and will remain so for the duration of the SBIR project. If the principal investigator is employed by a university, the letter must be furnished by the dean of the school or the departmental chairperson. If the principal investigator is employed by another for-profit organization, the letter must be signed by a corporate official. This documentation of the primary employment of the principal investigator is required for every application that is submitted, even one that is a revision of a previously submitted application. In the event that solicitation of this documentation would place the principal investigator's current employment in jeopardy should the grant award not be made, the applicant may delay submission of the documentation, provided the documentation is submitted no later than 30 days after receiving notice of a grant award, and provided that the applicant includes a statement with the grant application to the effect that solicitation of the documentation at this time would place the principal investigator's current employment in jeopardy, that the applicant will forward the documentation within 30 days of receiving notice of a grant award, and that the applicant understands that should it fail to provide the documentation, we may, at our discretion, immediately suspend or terminate the grant. If the principal investigator fails to furnish adequate documentation, the application may be returned without review. In the event a grantee is required to submit documentation of the principal investigator's employment, but fails to do so within 30 days of the date of the notice of grant award, we may immediately suspend or terminate the grant.

For both Phase I and Phase II, the research or R & D must be performed in its entirety in the United States (U.S.), that is, the States, territories, and possessions of the U.S.; the Commonwealths of Puerto Rico and the Northern Mariana Islands; and the District of Columbia.

## II. Definitions

The words and phrases that appear on the SBIR application form, or are needed in the application narrative, are

not readily defined. Therefore, for convenience and clarity, we have furnished the following definitions, which, except as noted, are taken from SBA's SBIR Program Policy Directive that implements this program and was published on January 26, 1993, in the Federal Register (58 FR 6144). This policy directive requires an agency to define in a separate section whatever terms it uses that are unique to either the SBIR Program, a specific SBIR solicitation, or a portion of the solicitation. The section must also include, at a minimum, specific terms as defined in the policy directive. Accordingly, in addition to the terms required by the policy directive, we are also defining the terms "Contract" and "Grant" and including the policy directive's definition of the term "Research and Development."

### A. Contract

A "contract" is an award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to furnish payment for the product or service.

### B. Grant

A "grant" is a financial assistance mechanism whereby either money or direct assistance, or both, is furnished to carry out approved activities.

### C. Socially and Economically Disadvantaged Individual

In accordance with the Small Business Administrations definitions (13 CFR Part 124), a "socially and economically disadvantaged individual" is defined as a member of any of the following groups:

- Asian-Pacific Americans
- Black Americans
- Hispanic Americans
- Native Americans
- Subcontinent Asian Americans

### D. Socially and Economically Disadvantaged Small Business Concern

A "socially and economically disadvantaged" small business concern is one—

- In which at least 51 percent is owned by one or more socially and economically disadvantaged individuals or, in the case of any publicly owned business, at least 51 percent of the voting stock is owned by one or more socially and economically disadvantaged individuals; and
- Whose management and daily business operations are controlled by one or more of the individuals.

### E. Research and Development

• Research and Development" or Research and Demonstrations is defined as any activity that is—

- A systematic, intensive study directed toward greater knowledge or understanding of the subject studies;
- A systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

### F. Small Business Concern

At the time of award of Phase I and of Phase II, a "small business concern" is one that—

- Is organized for profit, independently owned and operated, not dominant in the field of operation in which it is proposing, and has its principal place of business located in the U.S.;
- Is at least 51 percent owned or, in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; and
- Has, including its affiliates ("affiliation" is defined in 13 CFR 121.401), a number of employees (as defined in 13 CFR 121.407) not exceeding 500, and meets the other small business concern size regulation requirements found in 13 CFR 121. Business concerns, other than investment companies licensed, or State development companies qualifying, under the Small Business Investment Act of 1958 (15 U.S.C. 661 et seq.), are affiliates of one another when either directly or indirectly (1) one concern controls or has the power to control the other, (2) a third party or parties controls or has the power to control both, or (3) an identity of interest between or among parties exists so that affiliation may be found. Control can be exercised through common ownership, common management, and contractual relationships. Business concerns include, but are not limited to, any individual, partnership, corporation, joint venture, association, or cooperative.

### G. Subcontract

A "subcontract" is any agreement, other than one involving an employer-employee relationship, entered into by a Federal government funding agreement awardee calling for supplies or services

required solely for the performance of the original funding agreement.

#### *H. Women-Owned Small Business Concern*

A "women-owned small business concern" is a business that is at least 51 percent owned, controlled, and operated by a woman or women. "Control" is defined as exercising the power to make policy decisions; "operate" is defined as being actively involved in the day-to-day management.

#### III. Preparation of Grant Applications

The forms and instructions will be supplied to the applicant by the HCFA Grants Officer (see the **ADDRESSES** section of this notice) and are designed for use in applying for SBIR Phase I or Phase II research grants. The instructions contain the SBA policy directive's guidelines on proposal content and limitations.

Potential applicants are encouraged to contact the SBIR Coordinator (see the **FOR FURTHER INFORMATION CONTACT** section of this notice) for preapplication technical assistance and for more specific information on the research topics described in section VII. of this notice.

Health science research literature is available at academic and health science libraries and Regional Medical Libraries through a network supported by the National Library of Medicine. A list of Regional Medical Libraries and information about network services may be requested from the Public Information Office, National Library of Medicine, Bethesda, MD 20894, telephone (301) 496-6308.

Other sources that provide technology search and document services include the organizations listed below. They should be contacted directly for service and cost information.

*National Technical Information Service*  
5285 Port Royal Road  
Springfield, VA 22161  
(703) 487-4600

*NASA Industrial Applications Center*  
University of Pittsburgh  
701 LIS Building  
Pittsburgh, PA 15280  
(412) 624-5211

*North Carolina Science and Technology Research Center*  
Post Office Box 12235  
Research Triangle Park, NC 27709  
(919) 549-0671

*NASA/Florida State Technology Applications Center*  
State University  
System of Florida, 500 Well Hall  
Gainesville, FL 32611  
(904) 392-6626

*NASA/UK Technology*

University of Kentucky  
109 Kinlead Hall  
Lexington, KY 40506  
(606) 257-6322

#### *Aerospace Research Applications Center*

611 N. Capitol Avenue  
Indianapolis, IN 46204  
(317) 262-5003

*Kerr Industrial Applications Center*  
Southeastern Oklahoma State  
University Durant, OK 74701  
(405) 924-6822

#### IV. Submission of Grant Applications

Grant applications must be submitted to the HCFA Grants Officer (see the **ADDRESSES** section of this notice).

Applications must be postmarked by April 29, 1997. Applications mailed through the U.S. Postal Service or a commercial delivery service will be "on time" if they are received or postmarked on or before April 29, 1997.

Submissions by facsimile (fax) transmission will not be accepted.

Applications that do not meet the above criteria will be considered late applications. Respondents are cautioned that if their application is late, it will be returned without review.

#### V. Method of Selection and Evaluation Criteria

All Phase I and Phase II grant applications will be evaluated and judged on a competitive basis. Applications will be screened, and those found to be inadequate for review or programmatically unrelated to HCFA's mission will be returned to the applicant. Those passing the screening will be reviewed for technical merit. Each application will be judged individually, as described in this section. HCFA is under no obligation to fund any application or make any specific number of awards in a given topic area. It may also elect to fund no projects within a given topic area.

##### A. Review Process

Grant applications are subject to a review process involving two sequential steps. The first step is performed by a technical review panel composed primarily of Federal and non-Federal professionals selected for their competence in particular fields. The task of the panel is to evaluate applications for technical merit. The reviewers furnish a number rating, make an overall recommendation, and, on occasion, make highly specific recommendations related to the scope, direction, and conduct of the proposed research. The second level of review is made by the senior management of HCFA's ORD. ORD management

decisions are based on judgments about not only the technical merit of the proposed research, but also its relevance to our mission. Generally, HCFA may award a grant only if the corresponding application has been recommended for approval by the panel. However, applications recommended for approval are not automatically funded.

##### B. Review Criteria

- In considering the technical merit of each application, the following criteria and weights will be used:
  - The soundness and technical merit of the proposed approach—35 percent.
  - The potential of the research for technological innovation including the potential for commercial application—30 percent.
  - The qualifications of the proposed principal investigator, support staff, and consultant—20 percent.
  - The appropriateness of the budget—10 percent.
  - The adequacy and suitability of the facilities and research environment—5 percent.

##### C. Funding Decisions

When making funding decisions, ORD takes into consideration the following: (1) Ratings resulting from the technical evaluation process, (2) program relevance, and (3) applications.

##### D. Release of Grant Application Review Information

Following decisions on grant applications, their summary statements are mailed with a disapproval letter to principal investigators whose proposals have not been accepted.

##### E. Submission of Similar Grant Applications by the Applicant Organization

HCFA discourages the submission of more than one grant application submitted by the same applicant organization with essentially the same research focus: That is, a product or technology that, with nonsubstantive modifications, can be applied to a variety of purposes. In evaluating groupings of applications with a common focus or objective, technical review groups are in a position to easily identify multiple grant applications from the same organization for essentially the same project. In these cases, HCFA will give funding consideration to only one application.

#### VI. Considerations

SBA's SBIR Program Policy Directive (58 FR 6144) specifies that we furnish the following information:

### A. Awards

- There will be approximately 10 to 15 Phase I and/or Phase II awards in FY '97.
- The SBA Program Policy Directive permits the payment of a reasonable fee or profit under the SBIR program.

### B. Reports

The grantee organization will be required to submit semi-annual progress reports, a complete draft final report, and a final report. Additionally, a financial status report (SF-269A) must be submitted to the HCFA Grants Officer annually. The award will specify the schedule for these reports and place of delivery.

### C. Payment Schedule

Once an SBIR grant is awarded, the grantee organization will receive information and forms regarding requests for cash, manner of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis. Cost reimbursements may be requested monthly, quarterly, or at other periodic intervals. Advance payments may be requested on a monthly basis only.

### D. Limited Rights Information and Data

#### 1. Proprietary Information

Information contained in an unfunded grant application will remain the property of the applicant. HCFA may, however, retain copies of all applications.

If proprietary information is provided by a proposer in a proposal that constitutes a trade secret, proprietary, commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law, provided this information is clearly marked by the proposer with the term "confidential proprietary information" and provided the following legend appears on the title page of the proposal:

For any purpose other than to evaluate the proposal, this data shall not be disclosed outside the government and shall not be duplicated, used, or disclosed in whole or in part, provided that if a funding agreement is awarded to this proposer as a result of or in connection with the submission of this data, the government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement. This restriction does not limit the government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained in pages \_\_\_\_\_ of this proposal.

Any other legend may be unacceptable to the Federal government and may constitute grounds for removing the proposal from further consideration and without assuming any liability for inadvertent disclosure. The government will limit dissemination of the information to official channels only.

#### 2. Title to Property

Title to real property, equipment, and supplies acquired by a for-profit recipient under a financial assistance award or subaward will vest, upon acquisition, in the Federal government. However, the title may be transferred to the awardee upon termination of the project if the transfer would be more cost-effective than our recovery of the property. It is recommended that applicants consider leasing arrangements whenever possible. HCFA will generally not fund projects that require the acquisition of real property, equipment, or supplies.

#### 3. Rights in Data Developed Under the SBIR Grant

Rights in data, including software developed under the terms of any grant resulting from an application submitted in response to this notice, will remain with the grantee, except that the Federal government will have the limited right to use the data for internal Federal government purposes. These data will not be released outside the Federal government without permission of the grantee for a period of 4 years from completion of the project from which the data were generated. However, at the end of this 4-year period a royalty-free license will exist for HCFA to use, and to authorize others to use on its behalf, these data for Federal government purposes. At this time, HCFA is also relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties. This notice will be affixed to any reproductions of these data, in whole or in part.

#### 4. Copyrights

With prior written permission of the Grants Officer, the awardee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with HCFA's support. HCFA receives a royalty-free license for the Federal government and requires that each publication contain an appropriate acknowledgment of agency support and a disclaimer statement.

### 5. Patents

Small business concerns may normally retain the principal worldwide patent rights to any invention developed with HCFA support. The Federal government receives a royalty-free license for Federal government use, reserves the right to require the patentholder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the U.S. must normally manufacture it substantially in the U.S. To the extent authorized by 35 U.S.C. 205, the government will not make public any information disclosing a government-supported invention for a 4-year period to allow the awardee a reasonable time to pursue a patent.

### E. Profit or Fee

Absent a statutory prohibition, payment of a reasonable fee or profit will be made under the SBA's SBIR Program Policy Directive (58 FR 6144). Because the regulations set forth at 45 CFR 74.705, which provide that no profit or fee will be furnished to for-profit organizations through grants, do not invoke a statutory prohibition on paying a fee or profit, the SBA's policy directive applies to these SBIR grants.

### F. Joint Ventures and Limited Partnerships

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern in accordance with the definition included in this notice.

### G. Performance of Research and Analytical Work by the Applicant Organization

In Phase I, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the small business concern; that is, consultant fees and contracts to a third party for portions of the technical effort may not exceed 33 percent of the total proposed budget.

In Phase II, a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the small business concern; that is, consultant fees and contracts to a third party for portions of the technical effort may not exceed 50 percent of the total proposed budget.

### H. Terms and Conditions of Awards

Upon acceptance of a grant, the awardee must comply with the terms and conditions contained or referenced in the Notice of Grant Award document. These terms and conditions, constituting legal requirements imposed on a grantee by statute, regulations,

administrative policy, or the award document itself, comprise the following "standard" and "special" provisions:

- Standard Provisions—Terms and conditions required as part of each Notice of Grant Award.

1. SBIR Grant program legislation: The Small Business Innovation Development Act of 1982 (Public Law 97-219); SBIR Program Extension (Public Law 99-443); the SBA Reauthorization and Amendment Act of 1988 (Public Law 100-590); and the Small Business Research and Development Enhancement Act of 1992 (Public Law 102-564).

2. The SBA's SBIR Program Policy Directive published in the Federal Register on January 26, 1993 (58 FR 6144).

3. Regulations set forth at 13 CFR part 121.

4. The inclusion of special terms and conditions, if any (see below).

5. Regulations set forth at 45 CFR part 74 (Administration of Grants).

- Special Provisions—Additional terms and conditions judged necessary to attain the objectives for which the grant is being made, to facilitate post-award administration of the grant, to conserve grant funds, or to otherwise protect the interests of the Federal government.

1. Requirement for written progress reports and due dates.

2. Requirement for a draft final report and due date.

3. Grantees' responsibilities with respect to information contained in technical documents.

4. HCFA's rights to suspend or terminate the grant.

5. Protection of individually identifiable data.

6. Grantees' responsibilities with respect to presentation of information.

7. Key personnel.

8. Submission of data to the Federal government.

9. Submission of items developed to the Federal government.

10. Other special terms and conditions that are appropriate to the circumstances of the individual award.

The grant must be administered in accordance with the following regulations:

13 CFR Part 121—Small Business Size Regulations

42 CFR Part 52—Grants for Research Projects

45 CFR Part 46—Protection of Human Subjects

45 CFR Part 74—Administration of Grants

45 CFR Part 80—Nondiscrimination Under Programs Receiving Federal

Assistance Through the DHHS Effectuation of Title VI of the Civil Rights Act of 1964

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.

#### *I. Cost Sharing*

Cost sharing is not required nor will it be an evaluation factor in consideration of the proposal. However, due to the special nature of the SBIR Program, the applicant may choose to share the costs of a project. This may be done through cash or in-kind contributions. Most frequently, we expect that the applicant will contribute more labor or use unreimbursed equipment as the applicant's share.

#### *J. Additional Information*

This Federal Register notice is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained in this notice and the terms of any resulting SBIR grant, the terms of the grant are controlling.

Before award of an SBIR grant, HCFA may request the applicant to submit certain organization, management, personnel, and financial information in order to ensure responsibility of the applicant.

The Federal government is not responsible for any monies expended by the applicant before the award of any grant.

This notice is not an offer by HCFA and does not obligate HCFA to make any specific number of awards.

The SBIR Program is not a substitute for HCFA's existing unsolicited proposal mechanisms, and unsolicited proposals will not be accepted under either Phase I or Phase II of the SBIR Program.

The applicant may be required to certify that he or she has not previously been paid, nor is currently being paid, for essentially equivalent work by an agency of the Federal government. If a grant is made under this notice for a project, some of whose elements are being supported, or will be supported, by another Federal agency, HCFA and the applicant will negotiate a budget that reflects the elimination of any overlapping support.

This program is not covered by Executive Order 12372, "Intergovernment Review of Federal Programs." Executive Order 12372 provides for a State clearinghouse in

each State to review Federal programs. Research grants are exempt from this review.

#### VII. Research Topic Areas

This notice invites SBIR Phase I applications in the following areas. The topics are defined in general terms. They are intended to indicate where we believe we can properly offer assistance in the development of innovative technology. ORD will consider any idea that is within the general subject of a topic. In addition, ORD will review any idea that is within the general purview of HCFA, as described in section I of this notice. Applicants are reminded that the overall intent of the HCFA SBIR Program is to provide assistance to the development of products and processes that have commercial potential and not to the acquisition of products for HCFA's own use.

##### *A. High Quality and Effective Care*

HCFA invites ideas that would develop products to assist all participants in health care in assessing and monitoring the quality of care and level of care being furnished to patients. Projects should aim to develop tools for health care professionals, providers, and managers that permit them to examine patterns of services being delivered, and the health and social outcome of those services. Projects that would assist private organizations in developing patient guidelines and in conducting technology assessments are of interest. These tools should provide a way to monitor and measure the delivery of health care services and the outcomes of those services. They should also make possible a judgment about the quality of the care, the effectiveness of the care, or both. The technical efficiency with which care is delivered and the appropriateness of the overall outcome for the patient should be addressed.

##### *B. Management of Ambulatory Services*

HCFA invites ideas that would develop tools to monitor, assess, and control overutilization and underutilization of ambulatory services and products at all levels of the health care system. Apart from the inflation in the cost of each service, a significant cause of the rising cost of health care services is excessive utilization. Traditionally, utilization review techniques have been applied to high cost, acute services, such as surgery and hospitalizations. We wish to focus on physician services and other ambulatory services and products, for example, drugs, medical equipment, and testing. HCFA invites applications related to services or products commonly

associated with Medicare beneficiaries and Medicaid recipients, who are primarily the aged, the poor, the disabled, and persons with end-stage renal disease. Techniques to be explored involve systems both for retrospective utilization pattern review and for managing prospective interventions in individual physician or beneficiary and recipient service or product use. This area also includes broader management tools, based on information derived from utilization review, that promote or ensure more efficient and effective service delivery.

### C. Beneficiary Information and Assistance

HCFA invites ideas that may make the Medicare and Medicaid programs understandable to beneficiaries and recipients and that provide assistance to these individuals in their attempts to deal with the programs. Potential program users (Medicare and Medicaid beneficiaries) need to understand when they are eligible, what services or products are covered, and what their rights and responsibilities are within each program. (It is important to understand that detailed information on Medicaid must be assembled on a state-by-state basis). An example would be an information project that would assist health care consumers, including Medicare and Medicaid beneficiaries, by providing aggregate data on provider performance and utilization trends, discrete price information, and information on related copayments, etc.; in a sense, a "Blue Book for Consumers." Another example is obtaining payment for claims, one of the most frequent problems encountered by Medicare beneficiaries. The process of dealing with Medicare's fiscal intermediaries and carriers is difficult for many beneficiaries. Tools that would ease this process would be welcome. Beneficiaries also need to be able to decide whether they should join, or exit from, a health maintenance organization, and the advantages and disadvantages of the decision. Beneficiaries need to understand what considerations to take into account when long term care is a possibility. Similarly, beneficiaries need to be assisted in the decision about the purchase of health insurance in addition to Medicare. HCFA invites ideas in beneficiary communication and assistance approaches that are tailored to special populations (such as significant demographic, sociocultural, or disease-related groups of beneficiaries), as well as approaches that could be used by supplemental health benefit program sponsors (for

example, employers and unions) in assisting Medicare-eligible retirees. Applicants who are considering this topic should understand that the SBIR Program generally seeks to support the development of commercially viable products and that there is already a fair amount of existing commercial activity in this area.

### D. Program Efficiencies and Improvement

The existing systems for health care delivery and financing have undergone, and are continuing to undergo, changes due to new technology, legislation, regulation, and market forces. Major payers for health care are continually studying the feasibility of new approaches to improving the management of care, the delivery of care, and financing. Therefore, HCFA invites applications that focus on tools to assist in the goal of improved management of the Medicare and Medicaid programs. The term management is used in a broad sense. These could be tools that are directed toward providers who furnish services or products to Medicare beneficiaries or Medicaid recipients, organizations that handle the financing of care, organizations that oversee the quality of services and products, or the beneficiaries and recipients themselves, and State and local organizations that deal primarily with Medicare and Medicaid populations.

HCFA will consider any innovative idea that appears to have the potential for improving the programs for any of the several parties involved, and that has a potential for sale in the normal or commercial market. An example of an innovative idea is the development of improved computer-based case management systems for community care services. Case management programs are commonly being used to coordinate community-based care for frail elderly and other populations under Medicaid and other programs. Automated systems use client eligibility and assessment information to assist case management agencies in preparing appropriate plans of care based on the client's condition and select service providers. These systems would also interface with service approval or financial or billing systems to improve the cost-efficiency of case management programs. Proposed systems should complement or integrate existing mandated HCFA instruments (particularly functional assessment tools, minimum data sets, discharge planning, etc.). Redundant instruments will not be considered for funding.

### E. Other Health Care Research and Demonstrations

We encourage small business concerns to submit applications for proposed research in any area within the field of health care R & D.

### VIII. Other Required Information

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management.

Authority: Public Law 97-219, 96 Stat. 217-221; Public Law 99-443, 100 Stat. 1120; Sec. 108, Public Law 100-590, 102 Stat. 2989, 2994; Public Law 102-564, 106 Stat. 4249 (15 U.S.C. 638 (e) through (m)). (Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstration and Experiments)

Dated: December 17, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

[FR Doc. 97-2087 Filed 1-28-97; 8:45 am]

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[ORD-081-CN; ORD-082-CN; ORD-083-CN; ORD-091-CN; ORD-094-CN]

### Medicaid Program; New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: August and September 1995; October 1995; November 1995; July 1996; and October 1996; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction.

**SUMMARY:** In the following Federal Register documents delete the entry and description for the Montana Mental Health Access Plan as a "pending" section 1115 demonstration proposal.

- Federal Register document 95-30066, in the issue of December 11, 1995, page 63535, second column.
- Federal Register document 95-30559, in the issue of December 15, 1995, page 64443, first column.
- Federal Register document 96-824, in the issue of January 23, 1996, page 1772, first column.
- Federal Register document 96-23116, in the issue of September 11, 1996, page 47949 third column.
- Federal Register document 96-31237, in the issue of December 9, 1996, page 64916, third column.

In Federal Register document No. 95-30066, in the issue of December 11, 1995, on page 63536, first column, the narrative information under the heading "5. Disapproval Proposals" should read as follows:

"5. *Disapproval Proposals*