

OMB number	Approved CFR sections
0938-0723 ...	421.300-421.318
0938-0730 ...	405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, 424.24
0938-0732 ...	417.126, 417.470
0938-0734 ...	45 CFR 5b
0938-0739 ...	413.337, 413.343, 424.32, 483.20
0938-0742 ...	422.300-422.312
0938-0749 ...	424.57
0938-0753 ...	422.000-422.700
0938-0754 ...	441.152
0938-0758 ...	413.20, 413.24
0938-0760 ...	484 Subpart E, 484.55
0938-0761 ...	484.11, 484.20
0938-0763 ...	422.1-422.10, 422.50-422.80, 422.100-422.132, 422.300-422.312, 422.400-422.404, 422.560-422.622
0938-0768 ...	417.800-417.840
0938-0770 ...	410.2
0938-0778 ...	422.64, 422.111
0938-0779 ...	417.126, 417.470, 422.64, 422.210
0938-0781 ...	411.404-411.406, 484.10
0938-0786 ...	438.352, 438.360, 438.362, 438.364
0938-0787 ...	406.28, 407.27
0938-0790 ...	460.12, 460.22, 460.26, 460.30, 460.32, 460.52, 460.60, 460.70, 460.71, 460.72, 460.74, 460.80, 460.82, 460.98, 460.100, 460.102, 460.104, 460.106, 460.110, 460.112, 460.116, 460.118, 460.120, 460.122, 460.124, 460.132, 460.152, 460.154, 460.156, 460.160, 460.164, 460.168, 460.172, 460.190, 460.196, 460.200, 460.202, 460.204, 460.208, 460.210
0938-0792 ...	491.8, 491.11
0938-0798 ...	413.24, 413.65, 419.42
0938-0802 ...	419.43
0938-0818 ...	410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63
0938-0829 ...	422.620, 422.624, 422.626
0938-0832 ...	489
0938-0833 ...	483.350-483.376
0938-0841 ...	431.636, 457.50, 457.60, 457.70, 457.340, 457.350, 457.431, 457.440, 457.525, 457.560, 457.570, 457.740, 457.750, 457.810, 457.940, 457.945, 457.965, 457.985, 457.1005, 457.1015, 457.1180
0938-0842 ...	412.23, 412.604, 412.606, 412.608, 412.610, 412.614, 412.618, 412.626, 413.64
0938-0846 ...	411.1, 411.350-411.357, 424.22
0938-0857 ...	419
0938-0860 ...	419
0938-0866 ...	45 CFR Part 162
0938-0872 ...	413.337, 483.20
0938-0873 ...	422.152
0938-0874 ...	45 CFR Parts 160 and 162
0938-0878 ...	422
0938-0883 ...	45 CFR Parts 160 and 164
0938-0887 ...	45 CFR 148.316, 148.318, 148.320

OMB number	Approved CFR sections
0938-0897 ...	412.22, 412.533
0938-0907 ...	412.230, 412.304, 413.65
0938-0910 ...	422.620, 422.624, 422.626
0938-0911 ...	426.400, 426.500
0938-0916 ...	483.16
0938-0920 ...	438.6, 438.8, 438.10, 438.12, 438.50, 438.56, 438.102, 438.114, 438.202, 438.206, 438.207, 438.240, 438.242, 438.404, 438.406, 438.408, 438.410, 438.414, 438.416, 438.710, 438.722, 438.724, 438.810

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3134-N]

Medicare Program; Town Hall Meeting on Potential Facility Qualifications for Expanded Coverage of Percutaneous Transluminal Angioplasty for Carotid Stenting Procedures

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting to discuss potential facility qualifications and requirements to ensure that expanded Medicare coverage of Percutaneous Transluminal Angioplasty (PTA) for carotid stenting procedures would be safe, reasonable and necessary. Topics to be addressed include, but are not limited to, the degree of facility experience required, types of provider training programs to be developed and the rigor of these programs, supporting staff and specialty requirements, and specific stipulations that must be in place to ensure the correct use of this procedure in the appropriate patient population. Interventional radiologists, radiologists, neurological surgeons, cardiologists, neuro-radiologists, interventional cardiologists, interventional neurologists, vascular surgeons, neurologists, and other interested individuals are invited to this meeting to present their individual views on carotid stenting procedures. The opinions and alternatives provided during this meeting will assist us as we evaluate our policy on carotid stenting procedures for high-risk patients. The meeting is open to the public, but attendance is limited to space available.

DATES: The Town Hall meeting will be held on Tuesday August 17, 2004 at 8:30 a.m., e.s.t.

ADDRESSES: The Town Hall meeting will be held in the auditorium at the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Written Questions or Statements: Interested persons may send written comments by mail or electronically. We will accept written testimony, questions, or other statements, not to exceed 2-3 single-spaced, typed pages prior to, or within 14 days after the meeting. This time frame will allow us sufficient time for serious consideration and review of the submitted materials. Send written testimony, questions, or other statements to Rana Hogarth, OCSQ/CAG, C1-09-06, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244-1850 or to Rana.Hogarth@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Rana Hogarth, (410) 786-2112. You may also send inquiries about this meeting via e-mail to MEllis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare currently covers Percutaneous Transluminal Angioplasty of the Carotid Artery Concurrent with Stenting (CAG-00085N) in the context of Food and Drug Administration (FDA) approved Category B Investigational Device Exemption (IDE) Clinical Trials. Performance of Percutaneous Transluminal Angioplasty in the carotid artery used to treat obstructive lesions outside of these clinical trials is noncovered. Currently, Medicare is considering opening a National Coverage Determination to review coverage of carotid stenting procedures outside of the clinical trial setting. It is important that we establish facility qualifications and experience requirements that will ensure that carotid stenting procedures are performed in a manner which is safe, reasonable and necessary, and that would ensure beneficiaries needed pre- and post-procedure care.

II. Meeting Format

The initial portion of the meeting will be designed to elicit information on the appropriate experience requirements for facilities intending to offer carotid stenting procedures, suggestions for developing training programs, the rigor of these programs, and specific stipulations or limitations that must be in place to ensure appropriate use of this procedure. The remainder of the

meeting will be reserved for questions from interested persons.

Time for participants to make a statement will be limited according to the number of registered participants. Therefore, individuals who wish to make a statement must contact the individuals identified in the **FOR FURTHER INFORMATION CONTACT** section of this notice as soon as possible to register. Comments from individuals not registered will be heard after scheduled statements only, if time permits.

Written submissions will also be accepted.

III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410-786-0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Boulevard; Mailstop: C1-09-06; Baltimore, Maryland 21244, or by e-mail at Mellis@cms.hhs.gov. Please provide your name, address, telephone number, and, if available, e-mail address and fax number.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by close of business on August 10, 2004. In order to gain access to the building and grounds, participants must show to the Federal Protective Service or guard service personnel government-issued photo identification and a copy of their registration confirmation. Individuals who have not registered in advance will not be allowed to enter the building to attend the meeting.

Individuals requiring sign language interpretation or other special accommodations must provide that information upon registering for the meeting.

Authority: (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 17, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 04-14273 Filed 6-24-04; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Conference Grants to Support State Food Safety Task Force Meetings; Availability of Funds Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) in collaboration with the Centers for Disease Control and Prevention (CDC) is announcing the availability of conference grant funding for meetings of State Food Safety and Food Security Task Forces. The original announcement of availability of funding for State Food Safety Task Force Meetings, published in the **Federal Register** of January 24, 2000 (65 FR 3720), is superseded by this announcement. This revised announcement provides new policies that apply to the State Food Safety and Food Security Task Force Meetings Conference Grant Program. FDA views this program as an ongoing program announcement, contingent on the availability of funds. FDA anticipates providing approximately \$350,000 in direct costs only in support of this program in fiscal year (FY) 2004. It is anticipated that 50 awards will be made for up to \$7,000 per award.

DATES: The application receipt date is August 9, 2004, for the first year and March 15 for each subsequent year this program is in effect.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Cynthia M. Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA-531), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301-827-7180, e-mail:

cpolit@oc.fda.gov. Application forms PHS 5161-1 are available via the internet at: <http://www.psc.gov/forms> (Revised 7/00). Applications handcarried or commercially delivered should be addressed to 5630 Fishers Lane (HFA-531), rm. 2129, Rockville, MD 20857. An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. FDA cannot receive an application electronically.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Cynthia M. Polit (see **ADDRESSES**).

Regarding the programmatic aspects of this notice: Stephen Toigo, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs, Food and Drug Administration (HFC-150), 5600 Fishers Lane, rm. 12-07, Rockville, MD 20857, 301-827-6906, or access the Internet at: http://www.fda.gov/ora/fed_state/default.htm.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA and CDC view State-based Food Safety and Food Security Task Forces as important mechanisms for promoting food safety, food security program coordination, and information exchanges within each State. This grant announcement is intended to encourage the development of a Task Force within each State and to provide funding for Task Force meetings. Conference grant funding is available to States that have an existing Food Safety and Food Security Task Force, as well as to States that are in the process of developing such a Task Force. State Food Safety Task Force meetings should foster communication and cooperation among State and local public health and food safety agencies and other interested parties. Under this grant announcement, States may be awarded grants for up to 3 years for a maximum of \$7,000 per year in direct costs only, contingent on the availability of funds. Only one grant will be awarded per State per year.

Before submission of an application, the State shall designate one State public health or food safety agency to lead, coordinate, and host the Food Safety and Food Security Task Force and its meetings. The formation of Food Safety and Food Security Task Force meetings shall not interfere with existing federal-state advisory mechanisms.

Meetings covered by this notice will be supported under section 1701-1706 (42 U.S.C. 300u-300u-5) of the Public Service Health (PHS) Act. FDA's Conference Grant Program is described in the Catalog of Federal Domestic Assistance, No. 93-103. Applicants are limited to one State government agency per State. Applications submitted under this program are subject to the requirements of Executive Order 12372.

FDA urges applicants to submit workplans that address specific objectives of "Healthy People 2010." Applicants may obtain a paper copy of the "Healthy People 2010" objectives, Volumes I and II, for \$70 (\$87.50 foreign) S/N 017-000-00550-9, by writing to the Superintendent of Documents, P.O. Box 371954,