protein (acid-HP) and Asian-style sauces.

DATES: Submit written or electronic comments regarding the CPG at any time.

ADDRESSES: Submit written comments on the CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: http://www.regulations.gov.

Submit written requests for single copies of CPG Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6860. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the SUPPLEMENTARY INFORMATION section for electronic access to the document.


SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 23, 2006 (71 FR 29651), FDA announced the availability of draft CPG Sec. 500.500 Guidance Levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces. FDA received one comment on the draft CPG. The International Hydrolyzed Protein Council (IHPC) offered clarification for the following sentence found in the BACKGROUND section of the draft CPG: “Since 1996, many countries * * * have recommended or required that industry take steps to ensure that 3-MCPD is not detectable in acid-HP or Asian-style sauces at levels ranging from 0.01 parts per million (ppm) to 1 ppm.” IHPC suggested that we revise the sentence as follows: “Since 1996, many countries * * * have recommended or required that industry take steps to ensure that 3-MCPD in acid-HP or Asian-style sauces does not exceed levels ranging from 0.01 parts per million (ppm) to 1 ppm.” IHPC explained that using the phrase “not detectable” and then listing allowable levels is confusing. We concur with the comment and have revised the final CPG accordingly. FDA also revised the SPECIMEN CHARGES section in the final CPG to provide operational guidance regarding reference to the United States Code (U.S.C.) when citing the violation charged in a domestic seizure and reference to the Federal Food, Drug, and Cosmetic Act when citing the violation charged in an import detention. We also have made other editorial changes to the CPG for clarification.

This CPG is being issued as level 1 guidance consistent with FDA’s good guidance practices regulations (21 CFR 10.115). The CPG represents the agency’s current thinking on 3-MCPD in acid-HP and Asian-style sauces. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the CPG at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the CPG from the Office of Regulatory Affairs home page at http://www.fda.gov/ora under “Compliance Reference.”

Dated: March 14, 2008.

Margaret O’K. Glavin,
Associate Commissioner for Regulatory Affairs.
the elder in the care of the family and community. A LTC system with a foundation in HCBS will also comply with the United States Supreme Court interpretation of the Americans with Disabilities Act in Olmstead v. L.C., 527 U.S. 581 (1999). The 28 CFR 35.130(d) ruling obligates States and localities to provide care for persons with disability “in the most integrated setting appropriate to the needs of qualified individuals with disabilities.” An efficient and effective LTC system would make use of all available resources, integrating and coordinating services to assist families in the care of their elders.

The primary focus for planning and program development for AI/AN LTC is at the Tribal and urban community level. Tribes and communities have very different histories, capabilities, and resources with regard to LTC program development. Each Tribe or community will have different priorities in building LTC infrastructure. It is critical that the development of LTC services be well grounded in an assessment of need based on population demographics and rates of functional impairment. LTC services should be acceptable to elders and their families and consistent with community values in their implementation. The services should be a part of an overall vision and plan for a LTC system to support elders and their families.

There are a number of elements (Tribal sovereignty and the government-to-government relationship, the unique funding structure of Indian health, and the importance of the cultural context) that distinguish AI/AN LTC. Tribes and AI/AN organizations have found it useful to look both inside and outside of the Indian Health system (IHS, Tribal, and urban Indian health programs) for LTC strategies and models.

The planning and design of LTC services must identify the revenue source(s) that will support the delivery of care. Finding resources for LTC services presents a formidable challenge. Funds appropriated through the IHS (whether direct service or Tribal) can provide healthcare services which are part of a LTC system, but do not provide for a comprehensive set of LTC services and cannot support housing or social services of a non-medical nature. Programs funded through the Administration on Aging American Indian, Alaska Native and Native Hawaiian Program (e.g. Title VI A and Title VI C Family Caregiver Support Program) have been key elements in the LTC infrastructure in AI/AN communities. Additional Older American Act resources may be available through State Units on Aging and Area Agencies on Aging. Other resources are available to provide LTC services on a reimbursable basis for eligible AI/AN elders. The majority of formal LTC services in this country are funded by reimbursements from state Medicaid and HCBS programs. The Veterans Administration may be a source of reimbursement for LTC services for eligible AI/AN veterans. Federal housing programs are a potential resource in developing the housing component of the LTC infrastructure. Each of these resources has unique eligibility requirements. Development of reimbursement-based LTC services often requires an ongoing investment of funds to support delivery of services during the initial period of client recruitment, start-up of services, and the receipt of reimbursement for those services.

This grant program is designed to provide support for the development of AI/AN LTC, with funding for either assessment and planning, or program implementation. LTC services developed with support of this grant program must be those which the IHS has the authority to provide, either directly or through funding agreement, and must be designed to serve IRS beneficiaries. Most Tribes and urban communities are building toward their ideal LTC system incrementally, adding new or integrating existing services over time. The goal of this grant program is to support Tribes, Tribal Organizations, Tribal consortia, and Urban Indian health programs as they build LTC systems and services that meet the needs of their elders and that keep elders engaged and involved in the lives of their families and communities.

II. Award Information

Type of Awards: Grant.

Estimated Funds Available: The total amount identified for fiscal year (FY) 2008 is up to $600,000. The project period for the grants is 24 months in duration and each budget period is approximately 12 months. The award amounts are $50,000–$75,000 per year, depending on the project category. Continuation awards are subject to the availability of funds and satisfactory performance.

Anticipated Number of Awards: 8–10 awards will be made under this program announcement.

Project Period: Two Years (24 months).

Award Amount:
- $50,000 per year for Category 1—Assessment and Planning Awards.
- $75,000 per year for Category 2—Implementation Awards.

Category 1—Assessment and Planning awards will support the following activities:

a. Demographic assessment of the population and assessment of LTC needs on a population basis.

b. Evaluation of existing services and resources for LTC.

c. Evaluation of potential resources to fund LTC services.

d. Assessment of cultural and religious values regarding care of the elder for the population(s) served.

e. Assessment of elder preferences for type, structure, and setting of services.

f. Establishment of a comprehensive vision for LTC services with priorities for implementation.

g. Identification of potential funding sources for program development and for ongoing financing of service delivery.

h. The integration and incorporation of the above elements into a report or other document that guides LTC services/system implementation, including a plan for sustainability.

Category 2—Implementation awards will support the following activities:

Implementation of a service or group of services that add capacity to the LTC system of the applicant’s Tribe or organization. The implementation plan should be based on a comprehensive assessment and plan, including a business plan. The services should be designed to be self-sustaining at the end of the project period.

Applications must be for only one Project Type. Applications that address more than one Project Type will be considered ineligible and will be returned to the applicant. The maximum funding level includes both direct and indirect costs. Applications with budgets which exceed the maximum funding level for project period identified for a Project Type will not be reviewed.

III. Eligibility Information

1. The AI/AN applicant must be one of the following:

   a. A Federally-recognized Indian Tribe; or

   b. Tribal organization as defined by 25 U.S.C. 1603(o); or

   c. Urban Indian organization as defined by 25 U.S.C. 1603(h); or

   d. A consortium of eligible Tribes, Tribal organization or urban Indian health programs authorized by governing bodies to apply for and receive awards on their behalf under this program announcement.

   Applicants must provide proof of non-profit status with the application.

2. Cost Sharing or Matching—The ECILTC Grant Program does not require matching funds or cost sharing.
3. Other Requirements:
   A. A Letter of Intent (LOI) to apply is required and must be postmarked no later than May 2, 2008. The LOI is a mandatory but non-binding request for information that will assist in planning both the review and post award phase. There is no penalty for submitting a LOI and not proceeding with the grant application but a grant will not be reviewed if a LOI was not submitted. See Section IV.6.a for detailed instructions for submission of the LOI.
   B. The following documentation (as applicable) is required for an application to be considered complete:
      1. Tribal Resolution—A resolution of the Indian Tribe served by the project must accompany the application submission. An Indian Tribe that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities. Draft resolutions are acceptable in lieu of an official resolution. However, an official signed Tribal resolution must be received by the Division of Grants Operations (DGO) prior to the beginning of the Objective Review, July 21, 2008. If an official signed resolution is not received by July 21, 2008, the application will be considered incomplete, ineligible for review, and returned to the applicant without consideration. Applicants submitting additional documentation after the initial application submission are required to ensure the information was received by the IHS by obtaining documentation confirming delivery (i.e., FedEx tracking, postal return receipt, etc.).
      2. Tribal Consortium—If a consortium is submitting an application it must:
         • Identify each of the consortium member Tribes.
         • Identify if any of the member Tribes intend to submit a LTC grant application of their own.
         • Demonstrate that Tribes, Tribal organizations, urban Indian health programs, or Tribal consortia’s application does not duplicate or overlap any objectives of the other consortium members who may be submitting their own LTC grant application.
      Any application received from a Consortium that does not meet the requirements above will be considered ineligible for review.
         • Tribes, Tribal organizations, urban Indian health programs, or Tribal consortia’s receiving Category I (Assessment and Planning funding) in the FY2006–2007 [ITIS Elder Care Initiative grant cycle will be considered ineligible for FY2008 Category I (Assessment and Planning) funding unless they can demonstrate that the current application serves a different population than the FY2006–2007 grant. (e.g. a consortium may target different Tribes).
         • Tribes, Tribal organizations, urban Indian health programs, or Tribal consortias receiving Category II (Implementation) grants in the FY2006–2007 IHS Elder Health Care Initiative Grants cycle will be considered ineligible for FY2008 Category II (Implementation) funding unless they can demonstrate that they will be implementing an entirely new service or program (e.g. an applicant with current funding to implement an Adult Day Health Program may now apply for funding to implement a personal care program).

IV. Application and Submission Information

1. Applicant package may be found in Grants.gov (www.grants.gov) or at: http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp. Information regarding the electronic application process may be directed to Michelle G. Bulls, at (301) 443–6290.

Information regarding the Letter of Intent may be obtained from: Ms. Orlinda Platero, Office Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, (301) 443–2522, Fax: 301–594–6213.

The entire application package along with downloadable application instructions is available at: http://www.grants.gov. Details regarding the ECILTC Grant Program are available at: http://www.ihs.gov/MedicalPrograms/ElderCare/. Detailed application instructions for this announcement are downloadable on Grants.gov.

2. Content and Form of Application Submission:
   • Be single spaced.
   • Be typewritten.
   • Have consecutively numbered pages.
   • Use black type not smaller than 12 characters per one inch.
   • Contain a narrative that does not exceed ten-typed pages. See Section V for instructions for the content of the narrative. The ten page narrative does not include the detailed work plan with timeline, standard forms, Tribal resolutions or letters of support (if necessary), table of contents, budget, budget justifications, budget narrative, and/or other appendix items.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with the exception of the discrimination public policy.

3. Submission Dates and Times:
   Applications must be submitted electronically through Grants.gov by 12:00 midnight Eastern Standard Time (EST). If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant should contact Grants Policy Staff (UPS) at (301) 443–6290 at least fifteen days prior to the application deadline and advise of the difficulties that your organization is experiencing. The grantee must obtain prior approval, in writing (e-mails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies may be sent to the appropriate grants contact that is listed in Section P1.2., above.

Applications not submitted through Grants.gov, without an approved waiver, may be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the applicant, and will not be considered for funding.

4. Intergovernmental Review:
   Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions:
   Pre-award costs are allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR Part 74, all pre-award costs are incurred at the recipient’s risk. The awarding office is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated.
   • The available funds are inclusive of direct and appropriate indirect costs.
   • Only one grant will be awarded per applicant.
   • IHS will not acknowledge receipt of applications.

6. Other Submission Requirements:
   • If the applicant is unable to submit via Grants.gov and obtains a waiver from the standard application requirements, please use the following forms: SF–424, 424A, 424B, and certification forms, as appropriate. One original and two copies must be submitted to: attn: Norma Jean Dunne; Division of Grants Operations; 801 Thompson Avenue, Rockville, MD 20852. Copies of the forms may be found at: http://www.ihs.gov/
IHS.

• Under the new IHS application submission requirements, paper applications are not the preferred method. However, if you have technical problems submitting your application on-line, please contact directly Grants.gov Customer Support at: http://www.grants.gov/CustomerSupport.
• Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver request from GPS must be obtained.
• If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (emails are acceptable), to Michelle.Bulls@ihs.gov that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded by the applicant from: http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=forms.

Please be reminded of the following:

Applications submitted electronically must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1–888–227–2423. Please review and complete the CCR Registration Worksheet located on http://www.grants.gov/CCRRegister.

More detailed information regarding these registration processes can be found at http://www.grants.gov.

V. Application Review Information

Note: Only those programs or services which the IHS is authorized to provide, either directly or through funding agreement, can be supported by this grant program. UNLESS CONGRESS PROVIDES OTHERWISE, those services which are primarily housing or custodial in nature are not eligible for support (e.g. assisted living facility, board and care, or nursing home which is primarily custodial in nature). Supportive services delivered in those facilities, with the intent to promote the health and wellness of elders, are eligible for automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The IRS, DGO will download your application from Grants.gov and provide necessary copies to the cognizant program office. DGO will not notify applicants that the application has been received.

• You may access the electronic application for this program on http://www.Grants.gov.
• You may search for the downloadable application package either by the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.
• The applicant must provide the Funding Opportunity Number: HHS–2008–IHS–EHC–0001. E-mail applications will not be accepted under this announcement.

DUNS Number

Applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access http://www.dunandbradstreet.com or call 1–866–705–5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

Applications submitted electronically must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1–888–227–2423. Please review and complete the CCR Registration Worksheet located on http://www.grants.gov/CCRRegister.

More detailed information regarding these registration processes can be found at http://www.grants.gov.
funding. Programs and services developed with support of this grant program must be designed for the benefit of IHS beneficiaries.

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See “Multi-year Project Requirements” at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully.

1. Criteria

A. Category I (Assessment and Planning)

1. Introduction and Need for Assistance (35 Points)

Provide an understanding of the LTC needs of the elderly in the tribe or service area and identify the additional information needed for planning. The number of elders that will be affected by the program will be considered a factor in the review as will the relationship of the amount of funding requested to the number of elders to be served. The applicant should use the best data available, understanding that, for most programs, many of these data elements will not be available or be poor in quality and that improved data for future planning will be an outcome of this grant-funded project. Data that is not available should be noted as such and addressed in the work plan (Section 2).

Identify all information sources.

a. Currently available information for use in planning and service development:
   i. Currently available information regarding population and need for services.
   1. Demographics of the population and assessment of LTC needs on a population basis.
   2. Geographic and social factors, including availability of caregivers.
   3. Cultural and religious values regarding care of the elder for the population(s) to be served.
   4. Elder preferences for type, structure, and setting of services.
   ii. Currently available information regarding existing services and resources for LTC.
   1. Availability and organization of existing aging and LTC services, including services available to Tribal or community members provided by non-Tribal/non-AI/AN organization programs.
   2. Availability and organization of health services for the elderly, including Native healing systems.
   3. Assessment of the capacity of available LTC services to support care provided “in the most integrated setting appropriate to the needs of qualified individuals with disabilities” (Olmstead v. L.C).
   iii. Funding streams currently paying for LTC services.
   iv. Current collaborations in program development or service delivery.
   b. Current vision for LTC system/services and priorities for development.
   c. Elder care assessment and planning activities within the past ten years:
   i. Funding sources.
   ii. Dates of funding.
   iii. Summary of project accomplishments.
   iv. Relationship to the current proposal. Copies of reports will not be accepted.
   d. Unmet need for LTC services.
   e. Information needed for planning and service implementation which is not currently available.

2. Work Plan (35 Points)

This section should demonstrate the soundness and effectiveness of the applicant’s proposal. The work plan should be designed to produce as an end product the readiness to develop LTC service(s) and should include all information not already available. For an example of the information needed to demonstrate readiness to develop LTC service(s), see Section 1 Introduction and Need for Assistance in the Category II Implementation criteria.

Note that attendance and presentation at the AI/AN Long Term Care Conference and participation in periodic grantee teleconferences are a requirement of the grant and should be included as activities in the work plan.

a. State the proposed assessment or planning process.
   b. List the objectives clearly.
   i. Identify the data elements needed.
   ii. Indicate the function of each data element in the plan.
   c. Describe the approach to the project.
   i. Tasks.
   ii. Resources needed to implement and complete the project.
   iii. Timeline.
   iv. Specialized technical resources for data collection or analysis.
   v. Training needs.
   a. Include in work plan attendance and presentation at the annual AI/AN Long Term Care Conference.
   d. Identify the final product of the assessment/plan and the strategy for dissemination.
   e. Submit a work plan in the appendix which includes the following information:
   i. Action steps on a time line for implementation of the work plan.
   ii. Identify who will perform the action steps.
   iii. Identify who will supervise the action steps.
   iv. Identify who will accept and/or approve work products at the end of the proposed project.
   v. Include any additional training that will take place during the proposed project, who will conduct the training, and who will be attending the training.
   vi. Include the following information if consultants or contractors will be used during the proposed project, their position description and scope of work (or note if consultants/contractors will not be used):
      • Educational requirements.
      • Desired qualifications and work experience.
      • Expected work products.
      • Contractor’s supervisor.
      • Include a resume and letter of commitment in the appendix for potential consultant/contractor.

3. Project Evaluation (10 Points)

This section should show how progress on this project will be assessed and how the success of this project will be judged.

a. Describe and list outcomes by which this project will be evaluated.

Each proposed project objective and task of the work plan should be evaluated and the evaluation activities should appear on the work plan.

b. Identify the responsible person for the evaluation (need not be an outside evaluator).

4. Organizational Capabilities and Qualifications (10 Points)

This section outlines the broader capacity of the Tribe, Tribal organization, or urban health program to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and chain of responsibility for successful completion of the project outlined in the work plan.

a. Describe the organizational structure of the Tribe/tribal organization beyond health care activities.

b. Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other
grants and projects successfully completed.
  c. Describe what equipment (i.e., fax machine, phone, computer, etc.) and facility space (i.e., office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased through the grant.
  d. List key personnel who will work on the project.
    i. Identify existing personnel and new program staff to be hired.
    ii. Include in the appendix, position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience, requirements related to the proposed project and how they will be supervised. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities and who will determine if the work of a contractor is acceptable.
    iii. Note who will be writing the progress reports.
    iv. Indicate if a position is to be filled for a proposed position description.
    v. Note and address how additional personnel beyond those covered by the grant funds, (i.e., IT support, volunteers, interviewers, etc.), will be filled and if funds are required, list the funding source.
    vi. Indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual’s salary if personnel are to be only partially funded by this grant.

5. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the project program costs and justification for expenses for the entire grant period. The budget and budget justification should be consistent with the tasks identified in the work plan.
  a. Categorical budget (Form SF 424A, Budget Information Non Construction Programs) completing each of the budget periods requested.
  b. Include a narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allowability.
  c. Indicate any special start-up costs.
  d. Include a brief program narrative budget justification for the second year.
  e. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.

B. Category II (Program Implementation)

1. Introduction and Need for Assistance (35 points)

Provide an understanding of current need for and availability of LTC services for the elderly in the Tribe or service area. Identify the number of elders to be served. The number of elders that will be affected by the program will be considered a factor in the review as will the relationship of the amount of funding requested to the number of elders to be served. Demonstrate the necessary assessment and planning to successfully implement new service(s) and show that the services fit within a comprehensive vision or plan for elder care. If significant elements listed below are not available, programs should consider applying for Category I funding to support the assessment and planning activities necessary for successful program development.
  a. Demographic assessment of the population and assessment of LTC needs on a population basis.
    i. Population distribution. Number of elderly of different age and gender groups in the population.
    ii. Rates of functional impairment and numbers of elders with need for assistance in activities in daily living with adequate detail to project need for services.
  b. Geographic and social factors that affect access to services and availability of caregivers.
    i. Rural vs. urban; population density.
    ii. Family structure and organization.
    c. Assessment of cultural and religious values regarding care of the elder for the population(s) to be served.
  c. Assessment of elder preferences for type, structure, and setting of services.
  d. Evaluation of existing services and resources for LTC.
    i. Availability and organization of existing aging and LTC services. Include services available to Tribal or community members provided by programs or organizations that are not Tribal or AI/AN organizations.
    ii. Availability and organization of health services for the elderly, including Native healing systems.
  e. Capacity of existing LTC services to support care provided “in the most integrated setting appropriate to the needs of qualified individuals with disabilities” (Olmstead v. L.C).
    i. Availability of potential caregivers (formal and informal).
    ii. Training resources for formal and informal caregivers.
  g. Identification of potential resources for new LTC service.
    i. Funding for program development.
    ii. Funding for ongoing service delivery.
  h. Relevant Federal, 11-IS, Tribal and/or State standards, laws and regulations and codes and relevant licensure or certification requirements.
  i. A comprehensive vision or plan for LTC systems/services which incorporates the information above and identifies priorities for implementation.
  j. Unmet need for LTC services.

2. Work Plan (35 points)

This section should demonstrate the soundness and effectiveness of the applicant’s proposal. This includes both the work plan for program implementation and the underlying plan or strategy for sustainability of the service(s) past the point of grant support. Note that attendance and presentation at the AI/AN LTC Conference and participation in periodic grantee teleconferences are a requirement of the grant and should be included as activities in the work plan.
  a. Identify the LTC service(s) to be implemented and:
    i. Show how it is consistent with the results of the assessment/planning process described above (Introduction and Need for Assistance).
    ii. Integrates with existing LTC and health services.
  b. Summarize the business plan or plan for self-sufficiency and sustainability, including:
    i. Funding stream(s) to support ongoing services.
    ii. Clearly indicate whether the program will be self-supporting (and if so, when) or not. If not self-supporting, what will be the source of additional revenue for services?
    iii. Timeline with projections for client recruitment, expected revenue and shortfalls, resources for funds needed to bridge between onset of services and collection of reimbursement, etc.
  iv. Licensure or certification requirements.
  v. Indicate if Tribal revenue is expected to pay in part or in whole for services. A letter from the Tribal Council or administration indicating that these funds have been budgeted for this purpose should be included in the appendix.
  c. Describe the approach to implementation.
    i. Tasks.
    ii. Resources needed to implement and complete the project.
    iii. Timeline for implementation.
  iv. Specialized technical resources.
  v. Training needs.
organization, or urban health program to complete the project outlined in the work plan. This includes the identification of personnel responsible for completing tasks and chain of responsibility for successful completion of the project outlined in the work plan.

a. Describe the organizational structure of the Tribe/Tribal organization beyond health care activities.

b. If management systems are already in place, simply note it.

c. Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed.

d. Describe what equipment (i.e., fax machine, phone, computer, etc.) and facility space (i.e., office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased through the grant.

e. List key personnel who will work on the project.

i. Identify existing personnel and new program staff to be hired.

ii. Include position descriptions and resumes for all key personnel in the appendix. Position descriptions should clearly describe each position and duties, indicating desired qualifications and experience, requirements related to the proposed project and how they will be supervised. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities and who will determine if the work of a contractor is acceptable.

iii. Note who will be writing the progress reports.

iv. Indicate if a position is to be filled for a proposed position description.

v. Note and address how additional personnel beyond those covered by the grant funds, (i.e., IT support, volunteers, interviewers, etc.), will be filled and if funds are required, list the funding source.

vi. Indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual’s salary if personnel are to be only partially funded by this grant.

5. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the project program costs and justification for expenses for the entire grant period. The budget and budget justification should be consistent with the tasks identified in the work plan.

a. Categorical budget (Form SF 424A, Budget Information Non-Construction Programs) completing each of the budget periods requested.

b. Include a narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allowability.

c. Indicate any special start-up costs.

d. Include a brief program narrative budget justification for the second year.

e. Indicate and apply the current negotiated rate to the budget if indirect costs are claimed. Include a copy of the rate agreement in the appendix.

2. Review and Selection Process

In addition to the above criteria/requirements, applications are considered according to the following:

a. Letter of Intent Submission (Deadline: May 2, 2008); and

b. Application Submission (Application Deadline: June 20, 2006).

Applications submitted in advance of or by deadline and verified by the postmark will undergo a preliminary review to determine that:

• The applicant and proposed project type is eligible in accordance with this grant announcement.

• The application is not a duplication of a previously funded project.

• The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise, it may be returned.

c. Competitive Review of Eligible Applications (Objective Review: July 21–August 1, 2008).

Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed for merit by the Ad Hoc Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated and rated on the basis of the evaluation criteria listed in Section V.1. and V.2. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success, and assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of funding is not sufficient to support all approved applications. Applications
recommended for approval, having a score of 60 or above by the ORC and scored high enough to be considered for funding, are ranked. Additional considerations in final ranking include: geographic diversity among funded programs, diversity in population size among Tribes and communities served by funded programs, and unique features with regard to type of program planned or population served.

Applications scoring below 60 points will be disapproved and returned to the applicant. Applications that are approved but not funded will not be carried over into the next cycle for funding consideration.

3. Anticipated Announcement and Award Dates

Anticipated Award Notification: August 18, 2008.

Anticipated Award Start Date: September 1, 2008.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) will be initiated by DGO and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer, and this is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is the legally binding document. Applicants who are approved but unfunded or disapproved based on their Objective Review score will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted.

2. Administrative Requirements

Grants are administered in accordance with the following documents:

- This Program Announcement.
- Audit Requirements: OMB Circular A–133, "Audits of States, Local Governments, and Non-profit Organizations."

3. Indirect Costs: This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part 11–27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the DGO at the time of award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate is provided to the DGO.

Generally, indirect costs rates for IFIS grantees are negotiated with the Division of Cost Allocation (DCA) http://rates.psc.gov/ and the Department of Interior (National Business Center) http://www.nbc.gov/acquisition/ics/icshome.html. If your organization has questions regarding the indirect cost policy, please contact the DGO at (301) 443–5204.

4. Reporting

A. Progress Report. Program progress reports are required within 30 days of the completion of the semi annual report. These reports will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Status Report. Semi-annual financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

C. Reports. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due semi-annually. Financial Status Reports (SF–269) are due 90 days after each budget period and the final SF–269 must be verified from the grantee records on how the value was derived. Grantees must submit reports in a reasonable period of time.

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) the imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

5. Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contact(s)

For program-related information regarding the IHS Elder Care Program: Bruce Finke, MD, Nashville Area Elder Health Consultant, 45 Vernon Street, Northampton, MA 01060, (413) 584–0790, bruce.finke@ihs.gov.

For general information regarding this announcement: Ms. Orilda Platero, Office Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 326, Rockville, Maryland 20852, (301) 443–2522, Fax: (301) 594–6213.

For specific grant-related and business management information: Ms. Norma Jean Dunne, Division of Grant Operations, Indian Health Service, 801 Thompson Avenue, TMP 360–79, Rockville, Maryland 20852, (301) 443–5204, Fax: (301) 443–9602.

VIII. Other Information

The Department of Health and Human Services (HHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a HHS led activity for setting priority areas. This project will aid the accomplishment of Healthy People 2010 Focus Area 1—Access. Specifically, it will aid the accomplishment of objective 1–15, “Increase the proportion of persons with long-term care needs who have access to the continuum of long-term care services.” Potential applicants may obtain a printed copy of Healthy People 2010, (Summary Report No. 017–001–00549–5) or CD-ROM, Stock No. 0 17–001–00549–5, through the Superintendent of Documents, Government Printing Office, P.O. Box
I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide negotiation resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93–638, as amended. There is limited competition under this announcement because the authorizing legislation, Public Law 106–260, Title V, restricts eligibility to Tribes that meet specific criteria (Refer to Section III.I.A., ELIGIBLE APPLICANTS in this announcement). The TSGP is designed to promote self-determination by allowing Tribes to assume more control of Indian Health Service (IHS) programs and services through compacts negotiated with the IHS. The Negotiation Cooperative Agreement provides Tribes with funds to help cover the expenses involved in preparing for and negotiating with the IHS and assists eligible Indian Tribes to prepare Compacts and Funding Agreements (FAs). This program is described at 93.210 in the Catalog of Federal Domestic Assistance (CFDA).

The Negotiation Cooperative Agreement provides resources to assist Indian Tribes to conduct negotiation activities that include but are not limited to:

1. Determine what programs, services, functions, and activities (PSFAs) will be negotiated.
2. Identification of Tribal shares that will be included in the FA.
3. Development of the terms and conditions that will be set forth in the FA.

The award of a Negotiation Cooperative Agreement is not required as a prerequisite to enter the TSGP. Indian Tribes that have completed comparable health planning activities in previous years using Tribal resources but have not received a Tribal self-governance planning award are also eligible to apply.

II. Award Information

Type of Awards: Cooperative Agreement.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2008 is $240,000 for approximately twelve (12) Tribes. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: The estimated number of awards under the program to be funded is approximately 12.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

RIN 0917–ZA22

Reimbursement Rates for Calendar Year 2008

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001 (a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2008 for Medicare and Medicaid beneficiaries and beneficiaries of other Federal programs. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements. Public Law 106–554, section 432, dated December 21, 2000, authorized IHS facilities to file Medicare Part B claims with the carrier for payment for physician and certain other practitioner services provided on or after July 1, 2001.

<table>
<thead>
<tr>
<th>INPATIENT HOSPITAL PER DIEM RATE (EXCLUDES PHYSICIAN/PRACTITIONER SERVICES)</th>
<th>[Calendar Year 2008]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower 48 States</td>
<td>$1,811</td>
</tr>
<tr>
<td>Alaska</td>
<td>2,255</td>
</tr>
<tr>
<td>Outpatient per Visit Rate (Excluding Medicare)</td>
<td></td>
</tr>
<tr>
<td>Lower 48 States</td>
<td>$2,535</td>
</tr>
<tr>
<td>Alaska</td>
<td>423</td>
</tr>
<tr>
<td>Outpatient per Visit Rate (Medicare)</td>
<td></td>
</tr>
<tr>
<td>Lower 48 States</td>
<td>$2,150</td>
</tr>
<tr>
<td>Alaska</td>
<td>365</td>
</tr>
<tr>
<td>Medicare Part B Inpatient Ancillary per Diem Rate</td>
<td></td>
</tr>
<tr>
<td>Lower 48 States</td>
<td>$737</td>
</tr>
<tr>
<td>Alaska</td>
<td>650</td>
</tr>
<tr>
<td>Outpatient Surgery Rate (Medicare)</td>
<td></td>
</tr>
</tbody>
</table>

Established Medicare rates for freestanding Ambulatory Surgery Centers

Effective Date for Calendar Year 2008 Rates

Consistent with previous annual rate revisions, the Calendar Year 2008 rates will be effective for services provided on or after January 1, 2008 to the extent consistent with payment authorities including the applicable Medicaid State plan.


Robert G. McSwain,
Acting Director, Indian Health Service.