DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

May 8, 2000

Dear State Medicaid Director:
Dear State Children's Health Insurance Program Director:

As part of our effort to improve access to quality oral health services for children eligible for Medicaid and the State Children's Health Insurance Program (SCHIP), the Health Care Financing Administration (HCFA), in collaboration with our partners, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Indian Health Service (IHS), is soliciting applications from State Medicaid and SCHIP agencies for a new grant demonstration program, "Innovative Management of Dental Decay for Young Children Enrolled in Medicaid/SCHIP." This grant program (Catalogue of Federal Domestic Assistance Program Number 93.779) is designed to identify methods of innovative management of oral conditions among young children enrolled in Medicaid and SCHIP that result in oral health improvement and dental care cost savings.

This grant program will furnish administrative funds to assist States to provide and evaluate preventive and therapeutic regimens that are considered efficacious, but have not been widely implemented in dental practice or in publicly-funded dental services delivery programs. Specifically, the program is designed to demonstrate that such disease management interventions can reduce disease burden and associated dental repair costs. Ultimately, we will encourage States to incorporate successful intervention programs in their oral health care components.

Under this four-year demonstration program, HCFA will make awards to one or two States in the estimated amount of $220,000-$445,000 for an initial project period of up to 18 months. The enclosed grant announcement provides information regarding the goals and structure of the project, application procedures, eligibility requirements, and review criteria. **As identified in the announcement, the deadline for submitting an application is August 1, 2000. Proposals sent by commercial carrier must be received in the HCFA grants office on or before August 1. If delivered by the U.S. Postal Service, the postmark on the submission must be on or before August 1.**

Grant funds may be used for administrative tasks such as program development, provider training, data collection and analysis, and consultative or other contracts relevant to the project. We anticipate that most States applying for this project will wish to enter into an agreement for the scientific development and day-to-day management and operation of the project with an entity having strong research management experience involving oral health

benefits/status and cost assessment. Grant funds may **not** be used for payment of direct dental, medical and other services provided as part of the project. Direct services must be paid with funds from State Medicaid, SCHIP, or State-only programs.

This collaboration between HCFA, CDC, HRSA, and IHS is an outgrowth of increasing cooperation among Federal agencies concerned about oral health disparities and dental care access barriers among low income populations. This grant program is but one of several planned or in-progress activities which are designed to assist States in addressing and resolving long-standing oral health access problems in the Medicaid program. Since 1998, HCFA and HRSA have been involved in an interagency Oral Health Initiative designed to address oral health disparities through integration of Federal programs, partnering with other stakeholders, and integrating new technology and science to reduce oral disease burden.

An additional example of this growing interagency collaboration is found in a recently issued Request For Application (RFA) from the National Institute of Dental and Craniofacial Research (NIDCR) and a broad group of other Federal agencies. The NIDCR research program will involve multiple projects aimed at, among other things, developing interventions to prevent or reduce oral health disparities among children and their caregivers. We bring this RFA to your attention not only as an example of other interagency interest in reducing oral health disparities through research, but also as a possible opportunity for you to collaborate with a developing NIDCR research center as you consider a response to this HCFA solicitation.

If you have any questions regarding the HCFA grant announcement, please contact Dr. Don Schneider, Chief Dental Officer, at telephone (410) 786-5133, or e-mail dschneider@hcfa.gov.

We look forward to receiving your application.

Sincerely,

/s/

Timothy M. Westmoreland
Director

Enclosure

cc:
All HCFA Regional Administrators

All HCFA Associate Regional Administrators
for Medicaid and State Operations

William Maas
Director, Division of Oral Health
Centers for Disease Control and Prevention

John Rossetti
Chief Dental Officer
Health Resources and Services Administration

Eric Broderick
Principle Dental Consultant
Indian Health Service

Lee Partridge
Director, Health Policy Unit
American Public Human Services Administration

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors' Association

INNOVATIVE MANAGEMENT OF DENTAL DECAY FOR YOUNG CHILDREN ENROLLED IN MEDICAID/SCHIP

I. Purpose

The Health Care Financing Administration (HCFA), along with the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Indian Health Service (IHS), is soliciting project proposals from State Medicaid agencies and agencies administering the State Children's Health Insurance Program (SCHIP). The purpose of these projects is to demonstrate oral health improvement and dental care cost savings resulting from early case identification and innovative management of oral conditions among young children enrolled in Medicaid and SCHIP. This grant program will provide administrative resources which will assist States in providing and

assessing a constellation of services which include preventive and therapeutic regimens that are considered efficacious, but have not been widely implemented in dental practice or in publicly-funded dental services delivery programs. The objective of the program of Innovative Management of Dental Decay for Young Children Enrolled in Medicaid/SCHIP is to demonstrate that such disease management interventions can reduce dental disease, and reduce the need for conventional treatment and associated dental repair costs. Under this four-year demonstration program, the HCFA will make awards to one or two State Medicaid agencies in the estimated amount of $220,000-$445,000 for the initial project period of up to 18 months.

II. Background

Pediatric dental caries as a public health problem. Despite substantial reduction in pediatric tooth decay (dental caries) which has occurred in the U.S. over the past two decades, dental caries remains a major problem for many children, especially among children disadvantaged by low income, minority and immigrant status (Edelstein and Douglass, 1995). Progressive tooth decay causes children to suffer pain and infection, dysfunction in eating and speech, distraction and irritable behavior, and creates attendant learning limitations and issues of negative self-esteem. Healthy People 2000 updates show no reduction in caries prevalence among 6-8 year old children since the 1986 baseline, and a modest increase in the percentage of children with unfilled cavities. The National Institute of Dental and Craniofacial Research reports that 80 percent of tooth decay is isolated in only 25 percent of children (Kaste et al., 1996), with the most untreated disease occurring in those of low income. Children below 200 percent of poverty have substantially more dental disease, and more untreated dental disease than those above the 200 percent poverty level. Mexican-American and African-American children are about twice as likely to experience caries, and have higher levels of untreated caries than their non-Hispanic white counterparts (Vargas et al., 1998)

Preschoolers (2-5 years of age) below 200 percent of poverty have four to five times more cavities than children above 200 percent of poverty (Vargas et al., 1998). While Healthy People 2000 noted improvement in the percentage of young children who had access to dental care, a recent report from the Medical Expenditure Panel Survey did not show such improvement (Edelstein and Manski, 2000). In certain populations, such as American Indian and Alaskan Native children, early childhood caries has been found to be an especially significant public health problem as the condition affects more than 50 percent of preschool children (Bruerd and Jones, 1996). High rates of dental caries have also been reported for Head Start children. Chronically poor oral health is associated with failure to thrive in toddlers (Ayhan et al., 1996) and compromised nutrition in young children (Acs, 1992). Following therapeutic intervention, children with low weight and early childhood caries exhibit significant "catch-up" growth (Acs et al., 1998).

Pediatric dental caries as a concern in Medicaid/SCHIP. Children at elevated risk of acquiring dental caries are often covered for dental services by Medicaid, with its comprehensive Early and Periodic, Screening, Diagnostic and Treatment services, or by SCHIP programs which generally provide routine dental care. HCFA's Office of the Actuary estimates that combined Medicaid Federal and State

expenditures for dental care in 1998 account for about $2 billion in annual spending (HCFA, 1999). Of that amount, roughly 60 percent is expended on mandated dental care for children under 21 years of age (calculated from HCFA 2082 Report, FY 1996)

Recent studies of Medicaid expenditures in Louisiana and Iowa (Griffin, et al., 2000; and Kanellis, et al., 2000) report that substantial costs for treating dental caries in young children accrue to both dental and non-dental Medicaid program fiscal accounts. Non-dental costs arise from when traditional surgical services (such as hospital laboratory, ambulatory facility, and anesthesia fees) are required during repair of teeth of young children with extensive dental caries in the hospital operating room under general anesthesia. Extrapolating from the costs ($1,500-$2,000 per surgical case) and disease prevalence noted in these studies, it is estimated that combined Federal and State Medicaid expenditures for ambulatory hospital and dental care attributable to dental caries among young children may be $70-115 million annually. If early childhood caries prevalence among Medicaid beneficiaries in other States is more extensive than in Louisiana and Iowa--as is likely because of ethnic and cultural differences--or, Medicaid per case reimbursement is higher elsewhere, then the impact on overall Medicaid expenditures may be even greater. In addition, low income children covered by Medicaid and SCHIP who lack routine dental care often seek relief of pain and infection in hospital emergency rooms where costs are high and care is not definitive. Such palliative treatment usually only postpones the eventual need for restorative or surgical services. Anecdotal reports suggest that emergency room dental services are more costly than definitive dental care. Such expenses are reported as medical costs despite their strictly dental origin.

The fiscal impact of dental care for children enrolled in SCHIP is more difficult to estimate because the program is still in the early stages of being implemented and tracked. Fifty-four of fifty-six State and Territorial Title XXI plans submitted thus far to HCFA have included substantial routine dental services for most of the beneficiary population, despite the fact that dental benefits are optional under Title XXI. States may elect different mechanisms for implementing SCHIP; 44 percent have expanded Medicaid, 28 percent have developed separate, non-Medicaid programs, and 32 percent are developing combinations of an expanded Medicaid program and a separate SCHIP activity. One State recently reported that 22.8 percent of SCHIP claims for the first six months of program operation were expended on dental preventive and restorative care. This percentage is substantially higher than the amount expended by Medicaid for children's dental care--estimated at about 2-3 percent of all child health expenditures, but is in line with national estimates of the amount expended on dental care in comparison to medical office expenditures for children (Manski, 1999).

The low percent of child health expenditures attributable to dental care relative to total expenditures for children in Medicaid is partly indicative of long-standing access problems that have beset the Medicaid beneficiary population. These problems recently were highlighted by the DHHS Office of the Inspector General which reported that less than 20 percent of Medicaid children received any required preventive dental service (OIG, 1996). Reports of other populations with substantial reliance on Medicaid, such as Native American children, also indicate access problems; in 1996, only one Native American child in four had access to dental care (Breuard and Jones, 1996). In response to these reports, HCFA, in collaboration with the HRSA, sponsored a major conference in 1998 for Medicaid and dental

community stakeholders in an effort to identify solutions to access barriers (Spisak and Holt, 1999). The following year, the American Dental Association sponsored another major national leadership conference (ADA 1999) on Medicaid dental services, signaling its commitment to finding solutions. Subsequently, several States are considering implementation of State level access strategies that can be expected to increase costs to Medicaid, further enhancing interest in cost-saving, non-traditional program efficiencies and oral disease interventions.

Innovative management of dental caries (tooth decay). Traditional clinical caries management may be viewed as focusing on surgical repair of damaged teeth through the removal of diseased tooth structure and its replacement with biocompatible filling materials. New dental technologies and therapies provide potential for dramatic change in the way that this common dental disease is managed in the United States. Dental practice may now also include *medical*, as well as *surgical* management of dental caries. The concept of *medical* management recognizes that tooth decay is a transmissible, infectious bacterial disease and that interventions can be applied to prevent and control this infectious process (Anusavice, 1998, Ismail, 1998). It recognizes that decay is a chronic process with periods of damage and repair that can be controlled effectively in many people by life-long self- and professional care. In this management approach, dental caries is identified at its earliest stages and interventions are applied to stop disease progression, reverse early structural damage, and, when restoration is necessary because of excessive tooth destruction, teeth are repaired with simplified techniques that aim to avoid anesthesia and conserve tooth structure. Finally, in this model, affected children are placed into customized follow-up and prevention programs based on risk that has been assessed at the individual and/or community level and are monitored at intervals appropriate to assure that progression and recurrence are reduced or eliminated.

Health benefits and cost-savings of this medically managed approach may accrue to children and their families and to Medicaid/SCHIP programs. Care may be tailored to the level of disease activity so that children receive neither too many nor too few services, and disease is treated early and progression is checked. In this approach, interventions are designed to identify early disease when it can be stopped and reversed, reduce the need for conventional therapies, provide interventions that are less invasive, minimize physical pain and discomfort, and avoid exposure to local and general anesthesia (i.e., the Atraumatic Restorative Technique, or "ART," (Frencken et al., 1996; Kanellis, 1998; Mallow et al., 1998)). Primary teeth are retained until normal shedding instead of being extracted prematurely, thereby avoiding functional problems with speech and chewing and reducing downstream orthodontic problems.

Application of innovative oral health management models in the Medicaid and SCHIP arena may also enhance access by utilizing providers in addition to dentists to deliver specific components of the model. Appropriately trained caregivers including physicians, nurse practitioners, nurses, dental hygienists, dental assistants, social workers, peer counselors, community health workers and home visitors may each play appropriate roles in preventive service delivery, behavioral modification and dietary counseling, and case identification and referral. The model may allow for some services to be provided under the auspices of the dentist, but in locations other than the dental office, such as schools and pre-schools, Head Start settings, WIC facilities, community centers and homes, thus freeing dentist time for diagnostic and restorative treatment. Prevention of early dental caries also may be cost effective

(Ramos, 1999) and may decrease future needs for an expanded dental provider network over the longer term. An economic projection model of potential cost savings from innovative management of dental caries shows a potential savings of 12.5 percent in dental care expenditures for young children (Zavras et al., in press). These savings are generated primarily from reduction in hospital care for traditional surgical and restorative approaches.

III. The Project

Project structure and use of funds. The purpose of this four-year demonstration project is to provide States with administrative resources which will assist in developing, implementing, and assessing the health benefits and cost-savings attributable to preventive and therapeutic regimens which, although considered efficacious, have not been widely implemented in or assessed by the private dental sector or publicly-funded dental services delivery programs. Grant funds of approximately $220,000-$445,000 will be available for the initial budget period of up to 18 months. The number of grant awards depends upon the availability of funds and the technical quality of the applications. All future year funding is contingent upon acceptable performance and funding availability. States are encouraged to contribute additional funds or seek further funding support for this project from other agencies and organizations in order to expand the scope of the proposed study and to add evaluation components.

Grant funds *may only* be used for administrative tasks such as program development, provider training, data collection and analysis, research-related tasks, consultative or other contracts relevant to the project, and development of a budget neutrality model, if such a model is necessary (see discussion of "Budget Neutrality" below). These grant funds may not be used to obtain Federal matching funds under any Federal-State program. A State may elect to contribute State funds to improve or expand the administration of the proposed study; if these expenditures meet requirements under Medicaid, SCHIP, or another Federal-State program, Federal matching funds may be available.

> Example. Assume that the entire $445,000 grant amount is awarded to one State, and the total administrative expenditures incurred under the State's demonstration project are $485,000. In this example, $40,000 ($485,000-$445,000) represents additional State expenditures under the project. The grant award of $445,000 would be applied against the first $445,000 of the incurred administrative expenditures, and the remaining $40,000 may be claimable under Medicaid or SCHIP by the State at the appropriate Federal financial participation (FFP) for the type of administrative expenditures incurred.

Grant funds *may not* be used for payment of direct dental, medical or other services. Such payment must be made from State Medicaid, SCHIP, or State-only programs. Waiver of Federal requirements of "comparability," "statewideness" of services, or "freedom of choice of providers" may be needed if the project includes a modification of the Medicaid benefit package, such as introduction of a new service for the study population, or plans to require beneficiaries to obtain services only from specified providers (see discussion of "Waivers" below). Other waivers also may be needed. In addition, an

amendment to the Medicaid State Plan or SCHIP plan may be necessary. Grantee States will be responsible for obtaining necessary approval of waivers.

It is anticipated that most States applying for this project will wish to enter into an agreement for research design and evaluation, scientific development, and day-to-day management and operation of the project with an entity (e.g., a school of dentistry or medicine, school of public health, community-based health center, IHS dental facility, CDC Prevention Research Center, or other State or local health agency, etc.) having strong research management experience, especially in conducting studies involving oral health benefits/status and cost assessment.

In this regard, applicants are advised of a recently issued Request for Application (RFA) (DE-99-003) from the National Institute of Dental and Craniofacial Research (NIDCR) and a consortium of Federal agencies including the National Institute of Nursing Research, the National Institute of Child Health and Human Development, HRSA, IHS, CDC, HCFA, the National Institutes of Health's (NIH) Office of Minority Health, the Office of Behavioral and Social Science Research (NIH), and the Office of Research on Women's Health (NIH). Research supported by applications in response to this RFA will involve multi-project, multi-disciplinary studies aimed at, among other things, developing interventions to prevent or reduce oral health disparities in children and their caregivers. One requirement of the RFA is that, in developing centers for research to reduce oral health disparities, consortia be formed between academic health centers, community/migrant health clinics, IHS clinics, CDC Prevention Research Centers, State and local health care and health care financing agencies, and other providers of oral health to children and their caregivers. The endpoint of this research is to provide a database that can be used to generate and test interventions, including those involving funding of and access to oral health services, that will eliminate and prevent oral health disparities. These data also may be used to develop or modify policies pertaining to all phases and levels of prevention and treatment of dental caries in children. We bring this RFA to your attention as a possible opportunity to become involved in a developing center's research activities, and establish collaborations and partnerships with research institutions that will be responding to the RFA DE-99-003 referred to above.

Project goals and guidelines. Each of the following goals should be addressed, at least in part, in any application for these funds:

1. Identify innovative management interventions, which over time, can reduce dental disease among young children enrolled in Medicaid and/or SCHIP, shift care from surgical dental services to less expensive preservative care that seeks to avoid or delay operative intervention for as long as possible, reduce the number of dental restorations and replacement of restorations, decrease the need for orthodontic care by retaining primary teeth, reduce emergency room visits for dental emergencies, and reduce the use of general anesthesia in dental treatment.

2. Test approaches that result in improved access to dental care for the population by enhancing dentist and other provider participation in Medicaid and/or SCHIP, and increasing the number of children seeking and receiving diagnostic, preventive and therapeutic services.

3. Develop and document innovative management policies and procedures so that similar programs may be duplicated across the country. Documentation is needed, for example, for:
   - defining such items as the process for educating and enabling or "certifying" dentists and other providers to receive reimbursement for use of new procedures, therapies and technologies (which are "cutting edge" and may not be used widely in dental practice);
   - identifying the need for new dental claims codes not currently available as part of the American Dental Association's CDT-3 coding system and in the HCPCS coding system;
   - refining the protocols for, and utility of the techniques selected to assess risk of dental disease at the individual and/or community level;
   - describing how physicians and other health care providers may participate in triage, risk assessment, primary prevention, disease suppression and health maintenance, and
   - identifying approaches that take into account cultural/ethnic differences in beliefs and practices about health care, health care seeking, and health care delivery.

4. Control or reduce costs of oral health care (both per capita and for the demonstration population) by, for example, reducing the number and altering the type of treatments and repeat treatments; reducing the potential need for orthodontic services; reducing emergency room and general anesthesia use for dental problems; and using non-dentist personnel to provide novel services.

Additional guidelines for States in preparing applications for funding may be found in Appendix One, "Application Guidelines"

Project requirements*:*

Selection of interventions: States are encouraged to propose a project which utilizes several of many possible oral health management interventions. These interventions may include, but are not limited to:

- Triage of enrolled, young child populations to identify dental caries risk and heightened disease activity at the individual and/or community level;
- Primary caries prevention by dentists, other health professionals, and peer counselors through provision of family-level interventions, including prevention of infectious transmission of caries from mother to child, which may include emphasis of healthy dietary and hygienic behaviors;
- Tooth-level interventions using antimicrobial and fluoride preparations, such as fluoride varnishes which suppress bacterial flora and remineralize early caries;
- Caries management using new therapeutic techniques and materials (e.g., ART) that reduce the need for local and general anesthesia and help retain affected teeth until the child may better tolerate traditional dental repair.
- Maintenance and preventive care that is adjusted and proportional to assessed level of risk, effective in reducing caries progression, while avoiding services not demonstrated to be effective (Frame et al., 2000).
- Traditional preventive and therapeutic oral and medical services which may be organized and delivered in non-traditional settings or at variable frequencies.

Study population. The study population for the project must be young children enrolled in Medicaid or SCHIP. States may choose to provide oral health services and interventions to any range of young children, up to six years of age, e.g., ages 0-3, age 2 through age 5 years, etc. If the proposed intervention is directed at the child, but the parent is integral to delivery of the educational or clinical intervention, e.g., assuring the child's home care regimens, or attendance for regular professional care to reduce oral bacteria in the adult caregiver in efforts to delay caries transmission to the child, then the caregiver may be included in the project plan. The subject population must be of sufficient size to provide statistically meaningful comparisons among the new treatment group(s) and the current standard of care control group for this population. Standard statistical analyses with sufficient power to detect clinically meaningful outcomes should be incorporated into the research plan..

Data collection and analysis. The project must describe a method of data collection and analysis capable of tracking and discerning selected differences in the health status and associated costs/savings of the project's study and comparison populations. The project should provide a census of the enrollment characteristics of the population and evidence that the project can enroll and follow-up for patients to be included in the study. The project proposal should describe plans for protecting the confidentiality of any project-related information that identifies individuals. The proposal should indicate that such information is confidential and may not be disclosed directly or indirectly except for purposes connected with the conduct of the project, and assure that informed written consent of the individual is obtained for any disclosure.

Data and Safety Monitoring. Each project will need to describe an independent Data and Safety Monitoring Board (DSMB) consisting of individuals not connected in any way to the study. The DSMB

should consist at least of a chair who is knowledgeable in the area of study, a biostatistician, an ethicist, a pediatric dentist, a health economist and others whose expertise reflects the scientific focus of the demonstration project. The DSMB members are responsible for monitoring the safety of the patients and the internal progress of the project. They should meet annually to review these items and prepare an annual report which may be provided to HCFA as to whether progress is acceptable, patients are safe and the project should continue for an additional year. The DSMB should meet to review and approve the proposed protocol and manual of operations before any patients are entered into the project. The manual of operations will contain details about the intervention(s) to be tested, the research plan, protocol, etc. and will be used by study staff in guiding their day-to-day activities (i.e., it will help assure that everyone within the study is consistent in how they do things).

IV. General Provisions

Although applicants have considerable flexibility in developing demonstration projects under this solicitation, proposals for the Innovative Management of Dental Decay for Young Children Enrolled in Medicaid/SCHIP must comply with the following:

Duration of Proposed Program. States applying for a grant should plan to expend grant budgets in a period of no more than 18 months from the date of award.

Waivers. The grantee States must identify waivers or Medicaid or SCHIP requirements that they will require to carry out the demonstration project. Under Section 1115 (a)(1) of the Social Security Act, the Secretary may waive compliance with Medicaid State plan requirements (Section 1902) to further a demonstration project consistent with the objectives of the underlying statute.

In addition, Section 1115(a)(2) authorizes the Secretary to permit FFP for (1) expenditures for services or individuals who would not otherwise be covered, or (2) expenditures which would otherwise be denied based upon a limitation or condition imposed by Section 1903 of the Act. This authority, described as "costs not otherwise matchable," may be used to cover additional individuals or services not in the State plan or to permit the State to use alternative delivery systems.

Medicaid demonstration projects often require approval of such waivers or costs not otherwise matchable prior to implementation. Essentially, these waivers permit HCFA to pay for services that would otherwise not be reimbursable. For example, States may propose that service benefits may be available only to Medicaid enrolled beneficiaries who are included in the study population, or may require program participants to obtain their dental services through designated providers. In these circumstances, a waiver of Federal statutes requiring "comparability," "statewideness" of services, and "freedom of choice of providers" may be necessary. States should indicate whether or not they consider a waiver to be needed under this project.

A State, however, is *not* required to submit an application under the applicable waiver program(s) as part of its grant proposal. Typically, demonstration projects go through a developmental phase before

they need Medicaid waivers to become operational. Thus, most Medicaid demonstrations will need approval of demonstration waivers by the Federal Government before they enter their operational phase and begin operations. Hence, if the government deems that a waiver is necessary, the State will need to submit a waiver request prior to implementation of the project. Moreover, all applicable required demonstrations of cost-neutrality, cost-effectiveness, or budget neutrality remain in effect should any of the above noted waiver authorities be sought under this grant program. (Note that Medicaid waivers generally are not required for demonstrations which selectively alter reimbursement for covered benefits; such provisions are usually aimed at changing provider incentives for delivery of the service).

Title XXI, however, permits considerable flexibility in designing the benefit package for States with separate (non-Medicaid) SCHIP plans. In addition, "comparability" and "statewideness" are not factors in these programs since States may define geographic areas in which their programs will be implemented.

Budget Neutrality. In general, current Federal policy is that Federal Medicaid expenditures in a Section 1115 demonstration must not be higher than they would have been in the absence of the waiver. A budget neutrality cap is established at this expenditure level, and States cannot receive Federal matching funds in excess of this cap. If Medicaid 1115 waivers are pursued in the future as part of this demonstration, the demonstration will have to be budget neutral and will have to include a cap on applicable Medicaid expenditures. However, HCFA staff will be available to provide technical assistance for developing a model for budget neutrality.

Independent Evaluation. All grantees receiving awards under this grant program must agree to participate in an independent evaluation of the program's effectiveness. Grantees agree to provide health status, expenditure, utilization, outcome and additional data as appropriate to support the evaluation. States may be required to submit case studies of persons participating in the project. Applicants are encouraged to plan to submit an independent, annual evaluation of the project, and to identify individuals, not directly connected with the project, who may be called upon to conduct that assessment. (This evaluation differs from that conducted by the DSMB, in that the DSMB is focused on internal operations, whereas the independent evaluation addresses findings and other progress towards achievement of program goals). The applicant's budget should include funds which will enable key project personnel to meet at least annually with HCFA staff in Baltimore, Maryland, to describe the progress of the project.

Civil Rights. All grantees receiving awards under this grant program must meet the requirements of Title VI of the Civil Rights Act of 1964; Section 504 of the Rehabilitation Act of 1973; the Age Discrimination Act of 1975; Hill-Burton Community Service nondiscrimination provisions, and Title II, Subtitle A, of the Americans with Disabilities Act of 1990. States are encouraged to contact the Office of Civil Rights, DHHS, at (202) 619-0403 for technical assistance in developing a grant proposal that meets all the requirements of the civil rights and disability laws.

Intergovernment Review of Federal Programs. 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."

V. Applying For A Grant

Eligible Applicants. Applicants must be State Medicaid or SCHIP agencies. State Medicaid and SCHIP agencies are encouraged to work with each other, consumers and their families, other State agencies, community organizations, dental and other provider organizations, and other entities in developing applications.

Proposed Format. Appendix One contains a format for submitting a proposal.

Application Forms. In addition to the application, applicants must submit completed application forms included with this package: "Application for Federal Assistance (Standard Form 424)," "Budget Information (Standard Form 424A)" "Assurances (Standard Form 424B)," and "Disclosure of Lobbying Activities (Standard Form LLL)." Standard Form LLL also may be obtained by FAX from Dr. Don Schneider at the address in Section VII. Standard Forms 424, 424A, and 424B are also available at http://www.hcfa.gov/ord/Grantop.htm on the Internet. On Standard Form 424, Section 10, insert 93-779 for the "Catalog of Federal Assistance Number," and in Section 11, insert "Innovative Management of Dental Decay for Young Children Enrolled in Medicaid/SCHIP" as the descriptive title.

Deadline for Submission. The closing date for proposals submitted under this solicitation is **August 1, 2000**. If the proposal is sent by a commercial delivery service, it must be received in HCFA's grants office on or before August 1, 2000. If the proposal is mailed through the U.S. Postal Service, it must be postmarked on or before August 1, 2000. A proposal delivered by the U.S. Postal Service and postmarked after the closing date will be considered late. Late proposals will not be considered for an award.

An original proposal should be sent with **two copies** to:

Attn: Mrs. Linda Bianco
Health Care Financing Administration
AGG, Grants Management Staff
Mail Stop C2-21-15
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Phone: (410) 786-7080

Although States are not required to submit more than an original and two copies of an application, submission of additional five copies will help alleviate administrative burden and assist in expedient processing of incoming applications by the grant office.

VI. Application Review

An independent review of proposals will be conducted by a panel of experts. The panelists' recommendations will contain numerical ratings (based on criteria specified in Appendix Two), the ranking of all applicants, and a written assessment for each proposal. The recommendations of the panel will be reviewed by HCFA and ASPE. HCFA reserves the right to conduct site visits to those States receiving the highest ratings from the technical review panel. The number of States who may receive site visits will be determined based on the number of submissions and the number of proposals scored as technically acceptable by the technical review panel.

Final award decisions will be made by the HCFA Administrator after consideration of the comments and recommendations of the technical review panelists, comments and recommendations of the site visit teams (if conducted), and availability of funds.

Awards will be made by September 30, 2000. States will receive written notification of the final award decision. We expect to announce award decisions in September 2000.

VII. Additional Information

For additional information regarding this solicitation, please contact:

Don Schneider, D.D.S., M.P.H.
Chief Dental Officer, HCFA
Center for Medicaid and State Operations
Health Care Financing Administration
Mail Stop: S2-26-12
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Telephone: (410) 786-5133
E-mail: dschneider@hcfa.gov

For additional information about the NIDCR Project, RFA DE-99-003, Centers for Research to Reduce Oral Health Disparities, please contact:

Norman S. Braveman, Ph.D.
Associate Director for Clinical, Behavioral and Health Promotion Research
National Institute of Dental and Craniofacial Research
45 Center Drive, Building 45, Room 4AN-24B
Bethesda, Maryland 20892-6402
Telephone: (301) 594-2089
E-mail: Norman.Braveman@nih.gov

For information about the Centers for Disease Control and Prevention's "Prevention Research Centers," contact Dr. Barbara Gooch at the following address, or visit http://www.cdc.gov/prc on the Internet:

Barbara F. Gooch, D.M.D., M.P.H.
Division of Oral Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
4770 Buford Highway, MS F-10
Atlanta, GA 30341
Telephone: 770-488-6068
FAX: 770-488-6080
E-mail: bfg1@cdc.gov

VIII. Authority

Sections 1110, 1115(a) of the Social Security Act, As Amended (Catalogue of Federal Domestic Assistance Program Number 93.779, Health Financing Research Demonstrations and Experiments

Appendix One

Application Guidelines

The following guidelines are intended to assist States in preparing an application for funding under the program for Innovative Management of Dental Decay for Young Children Enrolled in Medicaid/SCHIP.

- The narrative portion of the proposal (Item 3 below) should not exceed 30 double spaced typewritten pages, using a font size no smaller than 11.5.
- Additional documentation should be appended; however, material should be limited to information relevant to the specific scope and purpose of the grant. Do not include critical details in an Appendix.

Recommended Proposal Format

A complete proposal consists of the narrative application (Item 3) plus the required material noted below. Application materials should be organized as follows:

1. Cover Letter From the Medicaid or SCHIP Director

A cover letter signed by an authorized individual on behalf of the lead organization. The letter should indicate the title of the project, the name of the lead organization and principal contact person, the amount of funding requested, the amount of any State matching funds committed for the planning and implementation phases, and the names of all organizations collaborating in the effort.

2. Project Abstract

A project abstract limited to one page. The abstract should serve as a succinct description of the proposed project and should include:

- The overall goals and organization of the project
- A description of the proposed target population, covered benefits/interventions, and data collection and analysis plans.

3. Narrative Application

The narrative application should provide a concise and complete description of the proposed project. The narrative or body of the application must not exceed 30 double-spaced pages using a font size not less than 11.5. Please do not rely on appendices to describe key details. This narrative should contain the information necessary for reviewers to fully understand the project being proposed and should be further organized as follows:

A. Provide a brief description of the operation of the oral health care delivery system in the State, with emphasis on Medicaid and/or SCHIP (to the extent that each of these programs will be the focus of the proposed project). Specify:

- the epidemiology of dental caries in the State and in populations served by State programs, emphasizing the oral health status of the population less than 21, and less that 6 years of age, to the extent that such information is available.
- the way in which oral health services are organized and delivered, including important relationships with other health care delivery organizations and entities;
- how the State's program is administered, identifying key organizational units with responsibility for day-to-day management of State programs.
- any problems of access, accessibility, quality, availability or other problems relating to oral health and oral health services, and any initiatives underway to resolve those problems.

B. Describe the proposed project. While planning for some areas may be incomplete, please include as much detail about the proposed project components as possible:

- *Innovative management model/hypotheses*: Identify and describe the problem(s) that the proposed innovative management model will address. Describe the hypotheses to be tested. Describe the types of services to be provided, and the scientific basis for assumptions that the selected innovative services will improve health outcomes and contain or reduce cost. Describe the way in which the management model will be offered to the beneficiary demonstration population, specifying the providers who will participate and their availability and accessibility to the population, and the mechanisms for delivery of the services. Describe the services offered and the care delivery system in the control community(s).

- *Target population*: Identify and describe populations in one or more cities, counties, or other defined areas of the State in which the demonstration will occur, and define a population which may serve as the control cohort. Both demonstration and control populations must include enough children within the age range 0-6 years to assure that there will be sufficient power to obtain statistical significance for analyses made over the course of the demonstration; assure that demonstration and control populations are comparable in socio-economic and oral disease status, and that other critical variables and confounders are controlled from the outset of the demonstration. A description of relevant local dental delivery system issues in the target population communities should be included;

- *Data collection and analysis plan*: For both the demonstration and control populations, specify the data to be collected, the method of data collection, and proposed plan for analyzing the data such that there is assurance of adequate program evaluation capability and statistical analyses necessary to measure the effect of interventions. At a minimum, data must be obtained annually for the demonstration and control populations on the utilization of dental and dentally-related services (e.g., in hospitals and ambulatory surgical facilities), the specific types of services provided to the populations, the dental and dentally-related costs of the services both per capita and for the total population, and the oral health status of the populations. If data will be obtained from sources other than currently available

administrative data sets, (or through integration of separate data sets), provide details of the data collection (e.g., chart audits, clinical epidemiologic assessments, etc) and sampling methods to be used.

- *Documentation*: Describe the documentation, protocols, and procedural manuals that will be developed during the course of the project, and how that documentation might be of use to other States desiring to duplicate the demonstration.

- *Partnerships*: Describe the participation and collaboration of State Medicaid program officials, and/or SCHIP program officials, if appropriate, and the dental provider community, and other relevant stakeholders (e.g., dental schools, medical societies, managed care organizations, State and local health agencies, community health centers, parent/community organizations, school authorities, Indian Health Service or Tribal authorities, WIC, Head Start) anticipated to play a role in the project.

- *IRB*: Indicate if there will be a need for IRB approval and, if so, describe the plan to assure that all IRB procedures and requirements are met.

- *Waivers/State Plan Amendments*. Provide an initial assessment of the need for waivers, if any, or amendments to the State plan that the State feels are necessary to implement the program. States may need to request Medicaid waivers to provide services not available to all Medicaid beneficiaries in the State or for other reasons, or may need to submit an amendment to the State Plan.

C. Describe the milestones and work products/tasks to be accomplished during the grant period. The purpose of this section is to outline clearly what the State hopes to achieve in the allotted four-year grant period.
   - Example of work products/tasks might include: an analysis of collected data, a completed waiver application, a training module for providers, or a health status survey instrument.
   - Timetables for accomplishing the major work products/tasks to be undertaken should be included and should include key dates relevant to the proposed project (e.g., State budget cycles and legislative sessions, if the project will require legislative/budget action).
   - Plans for conducting a periodic, independent evaluation of project progress, the operation of the Data and Safety Monitoring Board and plans for obtaining IRB approval.

D. Describe the project organization and staffing including:
   - Proposed management structure and how Project Administrator/Director will relate to the Principal Investigator, other key staff, and other partner and participating agencies.
   - As an appendix (not included in the 30 page limit), provide biographical sketches of the Project Administrator/Director (generally a State official), Technical Director or "Principle Investigator" (who may not be a State official) and other key project personnel, indicating their qualifications and prior experiences relevant to the project. Resumes for the key project personnel should be provided as an attachment.

E. Describe the support and commitments that have been pledged for the proposed project (e.g., cooperation from other State agencies, the State's executive and legislative branches, professional associations, collaborating academic and other institutions, key clinical service delivery sites and entities, fiscal agents or managed care entities with responsibilities for managing the State's Medicaid/SCHIP programs, etc.). Individual letters of support should be included as an appendix and are not included in the 30 page narrative limit.

4. Program Budget

The proposed budget for the project should distinguish the grant funded portion of the project from the direct services portion of the project.

Appendix Two

Review Criteria

1. Technical Approach (50 points)

The State must define how it will design and implement the project, addressing the following areas:

- description of current State and relevant, local level oral health care delivery system issues and concerns.
- innovative management model described with justification for selection of the constellation of proposed therapeutic and preventive services in terms of health benefits and cost savings.
- target and comparison populations identified. Additional points will be awarded for projects which incorporate American Indian and Alaskan Native populations into the study populations.
- hypotheses to be tested, and data collection and analysis plans are described, along with plans for gaining access to population data where administrative data sets are not available. Additional points will be awarded for projects which demonstrate an ability to collect or incorporate additional data not commonly available to State Medicaid or SCHIP agencies, and which expand the depth of the proposed analyses in assessing health improvement and cost savings.
- description of the potential for the model selected to be duplicated elsewhere and importance of the materials and documentation developed during the project to facilitate duplication.

2. Staff (20 points)

Identification of key program staff and evidence that the staff (including the Project Administrator/Director) are qualified and possess the experience and skills to implement and conduct the program within available time frames.

3. Project Feasibility (15 points)

The States should demonstrate that critical elements of the project will be accomplished in the proposed time frame. Key issues include potential for obtaining State-contributed resources for service delivery, difficulty in conducting necessary training and training materials, likelihood that providers of the services will be available, inclusion in the proposal of wrap-around services such as transportation and case management which might facilitate children's receipt of services, evidence that elements of the proposal are already underway in the State, etc.

4. Level of Commitment to the Project (15 points)

States must demonstrate their commitment to undertake this initiative, providing any evidence of support for the project, including evidence of coordination among and collaboration with other agencies and organizations. Additional points will be awarded to applications from States which demonstrate use of their own resources in combination with grant fund, or which can demonstrate funding support from other agencies and organizations.

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