physicians based on a fixed fee that is fair market value for services rendered, rather than a percentage of cost savings. Such contracts must meet the requirements of the anti-kickback statute (section 1128B(b) of the Act).

Notwithstanding the statutory prohibition, the OIG has given extensive consideration to whether it would be appropriate to protect individual gainsharing arrangements from OIG administrative sanctions through the issuance of favorable advisory opinions. Based on our review of a number of requests, we have concluded that they contain common elements that preclude our issuance of any favorable opinion. First, to date, the OIG has exercised its discretion to protect various arrangements from sanction only where such arrangements pose a minimal risk of fraud or abuse. By contrast, gainsharing arrangements pose a high risk of abuse. In order to retain or attract high-referring physicians, hospitals will be under pressure from competitors and physicians to increase the percentage of savings shared with the physicians, manipulate the hospital accounts to generate phantom savings, or otherwise game the arrangement to generate income for referring physicians. Given these pressures and the potential adverse impact on patient care from gainsharing arrangements, the OIG believes that immunizing such arrangements from sanction would be imprudent and inappropriate.

Second, gainsharing arrangements will require ongoing oversight both as to quality of care and fraud that is not available through the advisory opinion process. Apart from the potential for fraud and abuse, a critical inquiry is whether the arrangements have adequate and accurate measures of quality of care that would provide assurance that there is no adverse impact on patient care. Based on discussions with experts both within and without the Federal Government, the OIG has determined that any performance measures would require extensive verification through audits or review by an independent party on a continuing basis. The Office of Counsel to the Inspector General, which issues advisory opinions, has neither the resources nor the expertise to police a multitude of such arrangements on an ongoing basis.

Third, case by case determinations by advisory opinions are an inadequate and inequitable substitute for comprehensive and uniform regulation in this area. Were the OIG to issue a favorable opinion to one provider, that provider would have a significant competitive advantage in recruiting and attracting physicians to admit patients to its facility, since the physicians would have the opportunity to earn significant additional income not available at other institutions. The consequences would be that every hospital in the country would request an advisory opinion for its own program, and many would implement their own programs in the hope that their programs were close enough. Given the potentially serious adverse effects on patient care from improperly designed or implemented gainsharing arrangements, regulation of gainsharing arrangements requires clear, uniform, enforceable and independently verifiable standards applicable to all affected providers and not case by case decision-making.

E. Application to Other Arrangements

We are aware of reports that hospitals and physicians are engaging in a number of clinical joint ventures, including both freestanding specialty hospitals (e.g., heart, orthopedic, or maternity hospitals), and arrangements in which a high revenue generating unit or service (e.g., cardiology or cardiac surgery) of an existing hospital is restructured and legally incorporated as a separate hospital.

Typically marketed only to physicians in a position to refer patients to the venture and structured to take advantage of the exception in the physician self-referral law for physician investments in ''whole hospitals'', these ventures may induce investor-physicians to reduce services to patients through participation in profits generated by cost savings in clinical care. Accordingly, we believe such arrangements may also violate section 1128A(b)(1) of the Act, in at least some circumstances. In addition, such arrangements may implicate the anti-kickback statute (section 1128B(b) of the Act).

F. Conclusion

Absent legislative relief, section 1128A(b)(1) of the Act prohibits any gainsharing arrangements that involve payments by or on behalf of a hospital to physicians with clinical care responsibilities, directly or indirectly, to induce a reduction or limitation of services to Medicare or Medicaid patients. Parties interested in pursuing gainsharing arrangements that are currently prohibited by section 1128A(b)(1) of the Act should seek legislative relief. In the light of reports that some hospitals may already have such arrangements in place, the OIG will, in the absence of any evidence that an arrangement has violated any other statutes or adversely affected patient care, take into consideration in exercising its enforcement discretion whether a gainsharing arrangement was terminated expeditiously following publication of this Bulletin in the **Federal Register**.

Dated: July 6, 1999.

June Gibbs Brown,

Inspector General.

[FR Doc. 99–17889 Filed 7–13–99; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request, Survey of National Cancer Organizations Served by the NCI Office of Liaison Activities (OLA)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: Survey of National Cancer Organizations Served by the NCI Office of Liaison Activities. Type of Information Collection Request: New. Need and Use of Information Collection: The information to be collected in this survey is of vital importance to the National Cancer Institute's Office of Liaison Activities in determining the communication needs of the national cancer advocacy and voluntary organizations it serves and the desirability and usefulness of NCI's products and services. Information collected in this survey will be used to improve program services and make appropriate programmatic decisions. The respondents are leaders of organizations served by OLA and have a deep commitment to cancer advocacy in areas of cancer prevention, detection, treatment, control, and survivorship. They seek to improve the communication and collaboration between their organizations and the NCI. Frequency of Response: one time. Affected Public: Not-for-profit organizations. Type of Respondents: Organization leaders. The annual reporting burden is as follows: Estimated Number of Respondents: 150; Estimated Number of Responses per Respondent: 1; Average Burden Hours Per Response: .3841 and Estimated Total

Annual Burden Hours Requested: 57.61. The annualized cost to respondents is estimated at: $1,152.30. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or obtain a copy of the data collection plans and instruments, contact Ms. Kristie Dionne, Program Analyst, Office of Liaison Activities, NCI, NIH, Building 31, Room 10A06, 9000 Rockville Pike, Bethesda, MD 20892–2580, or call non-toll-free number (301) 594–3194 or e-mail your request, including your address, to *liaison@od.nci.nih.gov*.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: July 2, 1999.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 17927 Filed 7–13–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Impact and Costs of Sealants in Young Child Population

SUMMARY: Under the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 31, 1999, page 15367, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: The Impact and Costs of Sealants in Young Child Populations.

Type of Information Collection Request: Revision. Need and use of Information Collection; This study will assess the value (costs and effects) of providing dental sealants to the child population with erupted permanent posterior teeth (approximately ages 6–12) under alternative financial support programs in existing oral health care delivery systems and across two socioeconomic groups. The primary objectives of the study are to determine if various levels of dental insurance influence the use of dental sealants, if costs attributable to sealants in a payment program provide value in terms of reduced caries, and if providing dental sealants to specific tooth surfaces of children merits the investment of limited resources within a larger oral health care program. The findings will provide valuable information concerning: 1. Real disease reductions possible using dental sealants for age-appropriate child populations within the existing oral health delivery system, 2. the costs of, and estimated savings from, providing sealants rather than restorative care,and 3. the marginal benefits and cost benefits of adding sealants to ''normative'' caries prevention efforts in age-appropriate child populations.

Frequency of Response: On occasion. Affected Public: Individuals or Households, Businesses or other For-Profits. Type of respondents: Children, Parents, and Dentists. Estimated Number of Respondents: 1,200. Estimated Number of Responses per Respondent: 1. Average Burden hours per Response: .1200; and Estimated Total Annual Hours Requested: 766. The annualized cost to respondents is estimated at: $964. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The number of required respondents has been reduced significantly due to the proposed modification of the approach to meeting the objectives of the study. Data gathered from approximately 400 children enrolled to date under the study's insurance coverage will be supplemented by administrative data already collected from large numbers of children who are receiving dental care through private insurance, the Children's Health Insurance Program, and Medicaid. No contact with these children is required, and there will be no identifying information in the data obtained. The result of the proposed modification is that the respondent burden for the component of this study that involves direct contact with subjects is reduced substantially. The burden estimates are as follows:

	No. of respondents	No. of responses per respondent	Avg. burden/ response (hour)
Parents	500	4	.125
Children	400	4	.129
Dentists	300	1	.033

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and