

- A current product label, if applicable (preferably an electronic PDF file).

- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.

- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.

- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law. The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

Key Questions

- Key Question 1: For patients undergoing diagnostic coronary angiography to evaluate the presence/extent of Coronary Artery Disease (CAD) in order to decide on the necessity for coronary intervention, what is the impact of using an IVDx technique—when compared to angiography alone—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- Key Question 2: For patients undergoing Percutaneous Coronary Intervention (PCI), what is the impact of

using an Intravascular Diagnostic Device (IVDx) technique to guide the PCI procedure (either immediately prior to or during the procedure)—when compared to angiography-guided PCI—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- Key Question 3: For patients having just undergone a PCI, what is the impact of using an IVDx technique to evaluate the success of PCI immediately after the procedure—when compared to angiography alone—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- Key Question 4: How do different IVDx techniques compare to each other in their effects on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- During diagnostic coronary angiography for the evaluation of the presence/extent of CAD and the potential necessity of coronary intervention?

- During PCI to guide the procedure?
- Immediately after PCI to evaluate the success of PCI?

- Key Question 5: What factors (e.g., patient/physician characteristics, availability of prior noninvasive testing, type of PCI performed) influence the effect of IVDx techniques—when compared to angiography (or among different IVDx techniques)—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- During diagnostic coronary angiography for the evaluation of the presence/extent of CAD and the potential need for coronary intervention?

- During PCI to guide the procedure?
- Immediately after PCI to evaluate the success of PCI?

Dated: November 23, 2011.

Carolyn M. Clancy,
AHRQ, Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-12-12BW]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of

information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery—new—Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD).

As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the CDC has submitted a Generic Information Collection Request (Generic ICR): “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

To request additional information, please contact Daniel L. Holcomb, Reports Clearance Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the

sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

This is a new collection of information. Respondents will be screened and selected from Individuals and Households, Businesses Organizations, and/or State, Local or Tribal Government. Below we provide CDC's projected average estimates for the next three years. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 18,667.

Type of collection	Average number of respondents per activity	Annual frequency per response	Average number of activities	Average hours per response
Online surveys, Surveys, Focus Groups	7,000	1	4	40/60

Dated: December 7, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011-32027 Filed 12-13-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Financial Status Reporting Form for State Councils on Developmental Disabilities Program.

OMB No. 0980-0212.

Description

For the program of the State Councils on Developmental Disabilities, funds are

awarded to State agencies contingent on fiscal requirements in subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act. The SF-425, ordinarily mandated in the revised OMB Circular A-102, provides no accounting breakouts necessary for proper stewardship. Consequently, the proposed streamlined form will substitute for the SF-425 and will allow compliance monitoring and proactive compliance maintenance and technical assistance.

Respondents

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Status Reporting Form for State Councils on Developmental Disabilities Program	55	3	5.10	841.5

Estimated Total Annual Burden Hours: 841.5.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. *Email*

address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011-32051 Filed 12-13-11; 8:45 am]

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