Helping to End Lead Poisoning (HELP): A Questionnaire Study of Medicaid Providers' Self-Reported Attitudes, Practices, Beliefs, and Barriers to Childhood Blood Lead Testing

Application for OMB Clearance

Submitted by

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Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Emergency and Environmental Health Services
Lead Poisoning Prevention Branch
4770 Buford Highway, MS F-40
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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Lead is a part of the human environment as a result of industrialization. It is a heavy metal used in multiple materials and products. Lead poisoning results when lead enters the body. A number of human health effects, including mental retardation, coma, convulsions, reduced IQ, shortened attention span, hyperactivity, learning disabilities, and other health problems are associated with lead poisoning. Young children are more susceptible to lead poisoning because their developing nervous systems are more vulnerable to toxins and they readily absorb more lead than adults.

Analysis of the National Health and Nutrition Examination Survey (NHANES) shows that lead toxicity is a significant problem for children receiving care under Medicaid. These children were more than three times as likely to have high levels of lead in their blood as were children not receiving care under Medicaid. These results occurred despite the Health Care Financing Administration's, the agency responsible for administering the Medicaid program, mandatory screening requirements for children aged 1-5 years old. For nearly two-thirds of the Medicaid children identified through NHANES blood lead tests as having high lead levels, this was the first screening for lead they had ever received.

Although blood lead testing is important, it is ineffective unless it is performed when the child is young enough to receive the full benefits of effective environmental interventions. Thus, it was determined by the Centers for Disease Control and Prevention (CDC), Lead Poisoning Prevention Branch (LPPB) that more information is needed to understand the barriers Medicaid providers face when it comes to blood lead testing.

The data collection authority for this study is Section 301 of the Public Health Service Act (Attachment 1).

A. 2 Purpose and Use of the Information

The purpose of this data collection is to begin to assess physician attitudes, beliefs, practices and barriers regarding testing Medicaid children for lead poisoning. This study will focus on Medicaid providers in the Wisconsin cities of Sheboygan and Janesville. Wisconsin was selected as the state in which to conduct the pilot due to their ability to access real time Medicaid data. Janesville and Sheboygan will be compared for several reasons: 1) The modest disparity in lead testing penetration rates between the cities (Sheboygan 32.7; Janesville 27.8); 2) The similarities in population and urban characteristics; each has greater than 50,000 residents within the city limits (Janesville 59,366; Sheboygan 50,801) with established central business districts; and 3) The chance of a single patient receiving care in both cities is unlikely due to the fact that the cities are not contiguous. This is important so that physicians in one city are not providing care to patients in another city thus skewing the lead testing penetration rate within a city.

To date, funding for lead poisoning prevention services remains a critical issue for most states and local health departments. Gaining information on Medicaid provider attitudes, practices, beliefs, and barriers that would result in testing Medicaid-eligible children are important factors in CDC's determining what course of action and /or education and outreach strategies should be developed to increase lead testing for children under age six. For this reason,

descriptive, quantitative data are needed to identify and document the range of beliefs, perceived barriers, and perceived benefits of lead testing. Thus, to collect this data, a mailed questionnaire (Attachment 2) developed by knowledgeable investigators will be used in which Medicaid providers answer questions about their childhood blood lead testing practices. In this pilot study, Medicaid provider physicians in Sheboygan and Janesville, Wisconsin will participate through a mailed questionnaire process.

LPPB staff will use the information collected in this study to understand the barriers Medicaid providers face related to blood lead testing and to develop effective strategies that promote blood lead testing among Medicaid providers in Wisconsin. The results from this study will be useful to state and local health departments where blood lead testing penetration rates are consistently low for children on Medicaid. Results will be disseminated through presentations at conferences and through peer-reviewed publications. Participants may also request a summary of the major findings.

A.3. Use of Improved Information Technology and Burden Reductions

This collection of information will not use automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. It will be more practical and cost-effective to use a paper data collection instrument than to use a computerized survey. The study instruments require collection of only the minimum information necessary for the purpose of the project, therefore, no improved information technology will be utilized.

A.4. Efforts to Identify Duplication and Use of Similar Information

An extensive review of published scientific literature was conducted to locate other studies of Medicaid provider beliefs and barriers regarding childhood blood lead testing. We could not locate any other studies that assess Medicaid providers' self-reported attitudes, practices, beliefs and barriers to childhood blood lead testing.

A.5. Impact on Small Business or Other Small Entities

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. There are no legal obstacles to reduce the burden of this data collection.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection. The data collection complies with the guidelines of 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day notice was published in the *Federal Register* on November 9, 2004, Volume 69, Number 216, Page 64956 (Attachment 3). There were no public comments.

B. The following individuals were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and on the data elements:

Marjorie Coons
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Childhood Lead Poisoning Prevention Program
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Reghan O. Walsh
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Childhood Lead Poisoning Prevention Program
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A.9. Explanation of Any Payment or Gift to Respondents

CDC Childhood Lead Poisoning Prevention key chains will be given to physicians as an up front incentive with the survey questionnaire in order to improve response rates and to compensate participants for their time. According to Delnevo, Abatemarco, and Steinberg (2004), physician response rates to mail surveys are greatly improved by using up-front incentives. Up-front incentives also help with limited resources. According to Kellerman, & Herold (2001), limited resources that would be used for multiple follow-up mailings for non-responders could be shifted to an up-front incentive in order to ensure adequate response rates from physicians.

A.10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer has reviewed this OMB application and has determined that the Privacy Act is not applicable. Families participating in the Wisconsin Medicaid program in the cities of Sheboygan and Janesville must receive their health care through Health Maintenance Organizations (HMOs). Sheboygan and Janesville each have two HMOs that provide services to Medicaid patients. Participants for this study will be recruited from the Medicaid provider physician directories obtained from the HMOs that provide services in the cities of Sheboygan and Janesville. This list will be used to mail the questionnaires to Medicaid providers in the study's targeted areas.

The questionnaire will not collect personal identifiers from the respondents. The only demographic data to be collected is the respondent's gender. Any names or addresses that are provided or included in correspondence will be discarded as soon as follow up reminders are completed by the study investigators. Participant names will not be linked to questionnaires and researchers will not know which participants filled out the questionnaires. Responses in published reports will be presented in aggregate form and no individuals will be identified by name.

45 CFR 46 (Regulations for Protection of Human Subjects) apply to this project. Protocol 4459 was approved by the CDC Institutional Review Board (Attachment 4). In accordance with 45 CFR 46.117(c)(2), the Board approved a waiver of documentation of consent. The Board also approved alterations of the informed consent process by 1) waiving the required element of informed consent described in 45 CFR 116 (a)(4) regarding alternative treatment options that may be available to participants and 2) waiving the required element of informed consent described in 45 CFR 46.116(a)(7) regarding the inclusion of a contact person for research-related harm. Participants in this study will be giving their opinions on posed questions about their work practices. The study presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Participants will be given a written statement regarding the study in the form of a fact sheet (Attachment 5). Explanatory information provided to respondents is attached (Attachment 6).

A.11. Justification for Sensitive Questions

The purpose of this data collection is to begin to assess physician attitudes, beliefs, practices and barriers regarding testing Medicaid children for lead poisoning. Some questions may be considered sensitive by some portion of the population, particularly when the provider is asked for "feelings" regarding risk of lead poisoning for Medicaid children or about their routine testing practices. Questions #3 and #4 on the survey may be considered sensitive (Attachment 2). Question #3 is being asked to assess whether the respondent feels (believes) that Medicaid children are more at risk for lead poisoning than other children. We will use the respondent's answer to see if there is a correlation between their belief and testing practice of Medicaid children. Question #4 is being asked to assess whether the respondent routinely tests a child, any child, for lead poisoning. We will also use the respondent's answer to see if there is a correlation between their routine testing practices on all children versus Medicaid children. Both questions will help us develop interventions to increase blood lead testing among the Medicaid population.

A.12. Estimates of annualized Burden Hours and Costs

A. Annualized Burden Hours

The hour-burden for the questionnaire was estimated by testing the data collection instrument on 3 physicians, including 2 pediatricians. These are annualized rates and this is a request for a one-year study.

Estimated Annualized Burden Hours

Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours
Targeted Medicaid Providers in Wisconsin (mailed questionnaire)	13	1	10/60	2
Targeted Medicaid Providers in Wisconsin (telephone follow-up):"Yes"	60	1	10/60	10
Targeted Medicaid Providers in Wisconsin (telephone follow-up):"No" or mailed.	49	1	2/60	2
Total	122			14

Annualized Cost to Respondents

According to the Bureau of Labor Statistics, the hourly rate for Family Practitioners and General Practice physicians is $67.13.

Estimated Annualized Cost to Respondents

Respondents	No. of Respondents	Average Burden Per Response (in hours)	Average Hourly Rate	Respondent Costs
Targeted Medicaid Providers in Wisconsin (mailed questionnaire)	13	10/60	$67	$145
Targeted Medicaid Providers in Wisconsin (telephone follow-up):"Yes"	60	10/60	$67	$670
Targeted Medicaid Providers in Wisconsin (telephone follow-up):"No" no response via mail	49	2/60	$67	$109
Total	122			$924

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Item	Annualized Cost
CDC Personnel - Salary (1/2 time)	$18,000
Data Manager (1/4 time)	$11,250
Printing	$2,000
Mailing	$2,000
Up-front Incentives	$400
Total	$33,650

Costs for CDC personnel were estimated based on the project timeline and estimated work load for the project. There will be no contracted personnel. Costs for printing and mailing were estimated based on current printing costs and initial questionnaire packet mailing costs plus four follow up mailings. This is a one-year project.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

This is a comparison study between two communities in Wisconsin. In order to determine why some areas in Wisconsin have higher lead testing penetration rates than others, Medicaid providers in two areas will be surveyed. The city of Sheboygan has higher blood lead testing penetration rates for children under age 6 (32.7) than the city of Janesville with lower blood lead testing penetration rates (27.8). Questionnaires will be mailed to all physicians in Sheboygan and Janesville who 1) participate in the Medicaid program through a Health Maintenance Organization (HMO) and 2) provide care to adolescents in the area of pediatrics, family practice, and internal medicine (Sheboygan N=66; Janesville N=56). The questionnaires will be sent from and returned to the CDC LPPB in Atlanta, Georgia. Included in the questionnaire packet an incentive will be provided for completing the survey. The data from the completed questionnaires will be analyzed at the CDC LPPB in Atlanta, Georgia.

CDC LPPB and Wisconsin Childhood Lead Poisoning Prevention Program staff will use the information collected in this study to understand the barriers Medicaid providers face related to blood lead testing and to develop effective strategies that promote blood lead testing among Medicaid providers. Results will be disseminated through presentations at conferences and through peer-reviewed publications. Participants may also request a summary of the major findings.

Project Time Schedule	
Activity	**Time Schedule**
Questionnaires mailed	2 weeks after OMB approval
Follow-up mailings	1.5-2.5 months after OMB approval
Follow-up telephone calls	2.5-3.5 months after OMB approval
Analyze data collected	12 months after OMB approval
Publication	18 months after OMB approval

A.17. Reason (s) Display of OMB Expiration Date is Inappropriate

Exemption from displaying the expiration date for the OMB approval of forms is not being requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to certification for Paperwork Reduction Act Submissions.

B. Collections of Information Employing Statistical Methods

B. 1. Respondent Universe and Sampling Methods

Statistical methods will not be used to select respondents. The respondent universe consists of currently certified Medicaid providers in the cities of Sheboygan and Janesville, Wisconsin. The approximate number of participants to which the questionnaire will be sent is 122 (Sheboygan N=66, Janesville N=56). Due to the small respondent universe, questionnaires will be sent to all Medicaid providers in Sheboygan and Janesville, Wisconsin. We are expecting a 60% response rate which would place the potential number of participating physicians at 73.

We will obtain the Medicaid provider physician directory from the HMOs within Janesville and Sheboygan and then begin recruiting. We will send information to every physician in the directory.

B. 2. Procedures for the Collection of Information

This is a comparison study between two communities in Wisconsin. In order to determine why some areas in Wisconsin have higher lead testing penetration rates than others, Medicaid providers' self-reported attitudes, practices, beliefs, and barriers to childhood blood lead testing will be surveyed.

The city of Sheboygan has higher blood lead testing penetration rates for children under age 6 (32.7) than the city of Janesville with lower blood lead testing penetration rates (27.8). Questionnaires will be mailed to all physicians in Sheboygan and Janesville who 1) participate in the Medicaid program through a HMO and 2) provide care to adolescents in the area of pediatrics, family practice, and internal medicine (Sheboygan N=66; Janesville N=56). The questionnaires will be sent from the CDC LPPB in Atlanta, Georgia. Included in the questionnaire packet an incentive will be provided for completing the survey. A fact sheet will also be included. The fact sheet enclosed with the questionnaire will address the elements of informed consent (See Attachment 5). A completed and returned questionnaire will serve as proof of the physician's consent for participating in the study. The data from the completed questionnaires will be analyzed at the CDC LPPB in Atlanta, Georgia.

Respondents will not have advance notice of the questionnaire study and convenience will be maximized given that the respondents can complete the questionnaire at a time and location convenient to the respondent. Data coding and preparation will be done by the Principal Investigator and Data Manager within the CDC LPPB.

B. 3. Methods to Maximize Response Rates and Deal with Non-response

For this study, response rate is defined as the percentage of subjects meeting our eligibility criteria who return a completed questionnaire. In order to increase the response rates, the importance of the study will be emphasized through the inclusion of a fact sheet and in the introductory letter to the questionnaire. We believe a higher response rate will be attained if names are not associated with the questionnaire.

Participants' incentive will be mailed upfront with the questionnaire in order to improve response rates. In addition, all participants will receive reminder mailings (Attachment 7). After four weeks, they will receive a telephone call (Attachment 8) where they will be given the option to complete the questionnaire over the phone. Participant convenience will be maximized given that the participants can complete the questionnaire at a time and location convenient to the participant. Based on experience with physician response to mailed questionnaires, we anticipate the response rate for potential participants will be approximately 60%.

B. 4. Test of Procedures or Methods to Be Undertaken

All study materials have been evaluated in pilot tests involving 3 respondents. The pilot tests were used to more determine clarity and hours of burden of the questionnaire packet.

B. 5. Individuals Consulted on Statistical Aspects and Individual Collecting and/or Analyzing Data

The following individuals were consulted in reviewing the statistical procedures for this study:

Jaime Raymond, M.P.H., Data Manager
National Center for Environmental Health, CDC. Phone: 770-488-3616, Email: zvu0@cdc.gov

Curtis Blanton, Statistician
National Center for Environmental Health, CDC. Phone: 770-488-7114, Email: cgb9@cdc.gov

Jeffrey Havolina, Surveillance Manager
Wisconsin Department of Health and Family Services
Childhood Lead Poisoning Prevention Program Phone: 608-266-1826,
Email:havleja@dhfs.state.wi.us

CDC Investigator:
Principal Investigator (PI): Misha Walker, M.P.H., Public Health Advisor, Lead Poisoning Prevention Branch, Division of Emergency and Environmental Health Services, National Center for Environmental Health, CDC, 4770 Buford Highway, MS F-40, Atlanta, Georgia 30341. Phone: 770-488-7225, mnk2@cdc.gov
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List of Attachments

Attachment 1	Section 301 of the Public Health Service Act (42 USC 241)
Attachment 2	Data Collection Instrument – Mailed Questionnaire
Attachment 3	60-day *Federal Register Notice*
Attachment 4	CDC IRB Approval
Attachment 5	Participant Fact Sheet
Attachment 6	Questionnaire Introduction
Attachment 7	Medicaid Provider Reminder /Follow-up Letter
Attachment 8	Medicaid Provider Reminder Telephone Script

Attachment 1

Section 301 of the Public Health Service Act (42 USC 241)

Sec. 301 [241] (a) Research and investigations generally

Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section. The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)

(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains -

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and (D) a description of (i) each request received during the year involved -

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or

testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Source: U.S. Code Title 42, Chapter 6A, Subchapter II, Part A

Attachment 2

Data Collection Instrument - Mailed Questionnaire

Directions: Completely darken the circle next to all answers that apply to a question.

Survey Eligibility

1. Do you currently provide primary care to children 6 years old and younger?

1. Yes
2. No → Thank you, but you are not eligible to participate in this survey

2. Do you provide services to patients enrolled in Medicaid?

1. Yes (how long) _____ (continue to question #3)
2. No → Thank you, but you are not eligible to participate in this survey

If you are not eligible, please return this questionnaire, with the remaining questions left blank in the enclosed postage-paid envelope or call (770-488-3643) to have your name removed from the list of eligible participants.

3. Do you feel that the Medicaid children you provide for are more at risk for lead poisoning than other children?

1. Yes
2. No
3. Not sure

4. Do you routinely assess a child for lead poisoning at a HealthCheck visit?

1. Yes
2. No → Skip to question #6
3. Sometimes

5. If you answered yes or sometime to question #4, how do you determine if a child is at risk for lead exposure?

1. Parents or office staff complete a risk assessment questionnaire (a questionnaire designed to identify children at greater risk of lead exposure)
2. Standard questions are asked during the encounter
3. Other (please specify)_____

6. At what age do you routinely order a blood lead test for Medicaid children in your practice? Select all that apply.

1. Around the age of 6 months
2. Around the age of 12 months
3. Around the age of 18 months
4. Around the age of 24 months
5. Between 3-6 years with no test documented
6. At any time exposure may have occurred
7. I do not routinely order blood lead tests
8. Other (please specify)_____

7. When you or a member of your staff test for lead, how do you collect the blood lead sample? Select all that apply.

1. Fingerstick sample into microcontainer
2. Fingerstick sample on filter paper
3. Venipuncture

8. Where do your patients most often have their blood lead sample taken? Select all that apply.

1. At the clinic during the examination
2. At a laboratory in the same building or office complex as the clinic
3. At a laboratory in another building
4. At their WIC clinic
5. Other (please specify)_____.

9. What would be an incentive to testing children for lead on site? Please suggest.

_____
_____
_____
_____
_____

10. What factors can prevent or pose barriers to you in obtaining blood lead tests for Medicaid children at risk of lead exposure? Select all that apply.

1. The prevalence of venous lead levels ≥ 10µg/dL is low in my practice
2. Interventions available for children with lead levels 10-19 µg/dL are ineffective
3. Parents report that their child has had a blood lead test done elsewhere
4. My risk assessment of the patients indicates that they are at low risk for lead exposure
5. Medicaid does not adequately reimburse for blood lead tests
6. It is too inconvenient
7. There are other issues that are more important to review with parents
8. Parents refuse to have their child tested
9. Other _____

11. What factors or resources influence your current lead testing practices? Select all that apply.

1. Journal article
2. Opinion of colleague(s)
3. Your own experience
4. CDC recommendations
5. The extend of lead poisoning in my community
6. Parental demand
7. Federal law
8. Local or state lead testing guidelines
9 Media coverage
10. Other (please specify)_____

12. Are there local, state, or federal laws that require you to have children tested for lead poisoning?

1. Yes
2. No
3. Not sure

13. What is your gender?

1. Female
2. Male

14. Please indicate what your certification or licensure is.

1. Pediatrics
2. General/ Family Medicine
3. Pediatric Nurse Practitioner
4. Pediatric Physician Assistant

5. Other (please identify)_____

15. In what year did you receive your certification or licensure?

1. Before 1970
2. 1970-1980
3. 1981-1990
4. 1991-2000
5. 2001-2004

Thank you for your participation.

Attachment 3

Federal Register Notice

Form title	Number of respondents	Number of responses/ respondent	Average burden per response (in hrs.)
Supplementary Data Collection, Craniotomy Patient Report	9	58	27/60
Supplementary Data Collection, Spinal Fusion Patient Report	18	60	27/60
Supplementary Data Collection, Ventricular Shunt Patient	10	180	27/60
AUR Surveillance Monthly Report:			
ICP	30	12 (1×12)	2
Laboratory Technician	30	60 (5×12)	3
Pharmacy Technician	30	48 (4×12)	2
AUR Surveillance Contact Information	40	1	10/60
Antimicrobial Prescribing Practices	30	1	15/60

Dated: November 3, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–24892 Filed 11–8–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–05AD]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–498–1210 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–E11, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited 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) ways to enhance 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. Written comments should be received within 60 days of this notice.

Proposed Project

Helping to End Lead Poisoning (HELP): A Questionnaire Study of Medicaid Providers' Beliefs, Barriers, Knowledge, and Cues to Action for Childhood Blood Lead Testing—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

According to the United States Department of Health and Human Services (DHHS), lead poisoning is one of the most serious environmental threats to children in the United States. Very high blood lead levels in children can cause encephalopathy, coma, and even death. At lower levels, lead poisoning is a silent attacker because most children who are lead poisoned do not show symptoms. Low levels of lead poisoning are often associated with reductions in IQ and attention span, and with learning disabilities, hyperactivity, and behavioral problems. Because of these subtle effects, the best way to determine if a child has lead poisoning is by giving the child a blood lead test. Children eligible for Medicaid are typically at highest risk for lead exposure. DHHS policies require blood lead testing for all children participating in federal health care programs. However, most children in or targeted by federal health care programs have not been tested. This study will help to provide some of the reasons why most children are not being tested.

Although blood lead testing is important, it is ineffective unless it is performed when the child is young enough to receive the full benefits of effective environmental interventions. Thus, it was determined by CDC that more information is needed to understand the barriers Medicaid providers face when it comes to blood lead testing.

HELP is a comparison study between two communities in Wisconsin. To determine why some areas in Wisconsin have high blood lead testing rates and others do not, Medicaid providers in two areas will be studied. Community 1 has high and Community 2 has low blood lead testing rates. Questionnaires will be mailed to all Medicaid providers in these two Wisconsin communities. The questionnaires will be mailed from the Wisconsin Childhood Lead Poisoning Prevention Program in Milwaukee, Wisconsin. CDC will analyze the data from the questionnaires. CDC and the Wisconsin Childhood Lead Poisoning Prevention Program staff will use this information to understand the barriers Medicaid providers face concerning blood lead testing and to develop effective strategies that promote blood lead testing among Medicaid providers. There are no costs to respondents except their time to participate.

ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden hours
Targeted Medicaid Providers in Wisconsin	500	1	10/60	83
Total				83

Dated: November 3, 2004.

B. Kathy Skipper,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–24893 Filed 11–8–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0480]

The Minor Use and Minor Species Animal Health Act; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a new Office of Minor Use and Minor Species (MUMS) Animal Drug Development and is requesting comments on the implementation of the newly enacted MUMS Animal Health Act. This notice is intended to provide the public with contact information for the new MUMS office as well as to provide a venue for public comment.

DATES: Submit written or electronic comments by January 10, 2005.

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

FOR FURTHER INFORMATION CONTACT: Andrew Beaulieu, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301–827–2945, *abeaulie@cvm.fda.gov.* Alternatively, you may contact Margaret Oeller, Office of Minor Use and Minor Species Animal Drug Development, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 301–827–3067, *moeller@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The MUMS Animal Health Act became law on August 2, 2004 (Public Law 108–282). Several elements of the law became immediately effective on that date. These include the provisions for designation of MUMS drugs under section 573 and for conditional approval of MUMS drugs under section 571. The indexing provisions under section 572 of the law will only become effective upon publication of final implementing regulations. As mandated by the MUMS law, FDA has established the new Office of MUMS Animal Drug Development in the Center for Veterinary Medicine (CVM). FDA is requesting comments on any aspect of implementation of the MUMS legislation (see section II of this document). Requests for further information should be directed to the Office of MUMS Animal Drug Development (see **FOR FURTHER INFORMATION CONTACT**).

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24880 Filed 11–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0458]

Dietary Supplements; Strategy for the Further Implementation and Enforcement of the Dietary Supplement Health and Education Act of 1994; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its strategy for the further implementation of the Dietary Supplement Health and Education Act of 1994 (DSHEA). The strategy sets forth a series of specific, integrated research and regulatory measures, including guidance, regulations, and science-based compliance and enforcement mechanisms. Through implementation of these measures, FDA hopes to improve the transparency, predictability, and consistency both of the agency's scientific evaluations of dietary supplement product and ingredient safety, and of its regulatory actions to protect consumers against unsafe dietary supplements and dietary supplements making unauthorized, false, or misleading claims. FDA expects that this improved transparency will help engage stakeholders in the development of further measures to implement DSHEA.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the strategy for the further implementation of DSHEA to Vickey Lutwak, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1775, FAX: 301–436–2636, e-mail: *Vickey.Lutwak@fda.gov.*

Submit written comments 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.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Vickey Lutwak, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1775, FAX: 301–436–2636, e-mail: *Vickey.Lutwak@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In January 2000, FDA's Center for Food Safety and Applied Nutrition (CFSAN) issued its ''Dietary Supplement Strategy: Ten Year Plan'' (the 10-year plan) (accessible at *http://www.cfsan.fda.gov/~dms/ds-strat.html*). The 10-year plan sets as a goal a science-based regulatory program that fully implements DSHEA and affords consumers a high level of confidence in the safety, composition, and labeling of dietary supplement products. The 10-year plan sets forth a series of critical initiatives: (1) Improving the safety of products through, for example, regulations on current good manufacturing practice requirements for dietary supplements, guidance on premarket safety notifications for new dietary ingredients, and better adverse event report monitoring; (2) improving the labeling of products by, for example, clarifying what data and information are needed to substantiate structure/function and related claims in the labeling of a product; (3) clarifying the boundaries between dietary supplements, conventional foods, and drugs; (4) taking enforcement action against unsafe products and products whose labels are inaccurate or

Attachment 4

CDC IRB Approval

-----Original Message-----
From: McCleary, Jennifer
Sent: Thursday, January 27, 2005 11:59 AM
To: Thomas, Kamilah
Cc: Sowell, Anne; Young, Joni; Posid, Joe
Subject: 4459: IRB Approval of New Protocol (Expedited)

DATE: 1/27/2005

FROM: IRB Administrator
Human Subjects Activity
Office of Science Policy and Technology Transfer, OD/CDC

SUBJECT: IRB Approval of New Protocol #4459, "Helping to End Lead Poisoning (HELP): A Questionnaire Study of Medicaid Providers' Self-Reported Attitudes, Practices, Beliefs and Barriers to Childhood Blood Lead Testing"

TO: KAMILAH THOMAS, MPH [KIT8]
NCEH/EEHS

New protocol #4459 has been approved by CDC IRB "C" for the maximum allowable period of one year; therefore, protocol #4459 will expire on 1/23/2006. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category 4.

The Board approved a waiver of documentation of consent in accordance with 45 CFR 46.117(c)(2). The Board also approved alterations of the informed consent process by: 1) waiving the required element of informed consent described in 45 CFR 46.116(a)(4) regarding alternative treatment options that may be available to participants and 2) waiving the required element of informed consent described in 45 CFR 46.116(a)(7) regarding the inclusion of a contact person for research-related harm.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 1/23/2006.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Subjects Activity at (404) 371-5980 or e-mail: huma@cdc.gov.
Jennifer McCleary
cc:
Joe Posid
Anne Sowell
Joni Young

Attachment 5

Participant Fact Sheet

Fact Sheet
Title: Helping to End Lead Poisoning by 2010

What is the purpose?
You are invited to complete a mailed questionnaire for a research study entitled Helping to End Lead Poisoning (HELP 2010). Children eligible for Medicaid are typically at a higher risk for lead poisoning as compared to their non Medicaid counterparts. Blood lead testing is known to be an important component in reducing the harmful effects of lead poisoning. However, blood lead testing is ineffective if not performed when the child is young enough to receive the full benefits of effective environmental interventions. The purpose of this questionnaire is to learn more about ways to help increase the blood lead testing rates of Medicaid healthcare providers.

Why have you been asked to take part in this study?
You have been asked to be in this study because you are a Medicaid healthcare provider in a community that has been selected for this program.

What will you be asked to do?
You will be asked to complete a mailed questionnaire. We estimate that the questionnaire will take about 10 minutes of your time to complete. Your participation is for this one time only. We will ask you various questions regarding barriers to lead poisoning testing and your opinions on testing for lead. Your insights and opinions on this subject are important to us. There are no right or wrong answers.

What are the benefits of your participation?
Participants will be able to explore their feelings and beliefs about issues related to blood lead testing. For society, this research may have benefits in the development of effective methods and strategies that help increase physician blood testing rates in young children eligible for Medicaid.

Are there any risks?
There are no known risks of completing the mailed questionnaire.

Are there any costs?
There is no cost to participate.

Confidentiality:
If you agree to participate in this study, your participation is voluntary. You have the right to stop your participation at any time. You also have the right to refuse to answer certain questions. All the information you provide will be kept in a confidential manner unless compelled by law. You do not need to provide your name and we will not record it, if you do so. All questionnaires will be analyzed without names and other identifiers in order to safeguard your privacy. Every effort will be taken to protect the identity of the participants in the study. You will not be identified in any report or publication of this study or its results.

Who can I contact to answer questions about the study?
If you have questions about this study, you may call Misha Walker, 4770 Buford Highway MS F40 Atlanta, GA 30341 phone: 770-488-7225. This study has been reviewed and approved by the Centers for Disease Control and Prevention, National Center for Environmental Health, Institutional Review Board on Research Involving Human Subjects. If you have questions about your rights as a study participant, or are dissatisfied at any time with any aspect of this study, you may contact—anonymously, if you wish – the Centers for Disease Control and Prevention, National Center for Environmental Health, Institutional Review Board, 1600 Clifton Rd. MS C-25 Atlanta, GA 30333 (404) 639-4500.

Attachment 6

Questionnaire Introduction

Date:

Dear Healthcare Provider,

The Lead Poisoning Prevention Branch of the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health and the Wisconsin Childhood Lead Poisoning Prevention Program are conducting a study entitled, "Helping to End Lead Poisoning (HELP): A Questionnaire Study of Medicaid Providers' Self–Reported Attitudes, Practices, Beliefs and Barriers to Childhood Blood Lead Testing."

We are distributing mailed questionnaires to Healthcare Providers, who provide care to children enrolled in the Medicaid program in the cities of Sheboygan and Janesville. In order to determine the barriers related to blood lead testing, descriptive, quantitative data are needed to identify and document the full range of attitudes, practices, beliefs and barriers to testing children for lead poisoning. To obtain this information, we are asking for you or a knowledgeable member of your staff to complete the multiple choice questionnaire found on the following pages.

As a reminder, results will be reported in aggregate form. Participant names will not be linked to questionnaires and researchers will not know which participants filled out the questionnaires.

Your participation is very important to the success of this study and we hope that you choose to participate.

Enclosed you will find a CDC Childhood Lead Poisoning Prevention keychain as a token of our appreciation and a fact sheet with additional information about the study.

When you complete the questionnaire, please return it in the self-addressed stamped envelope or mail it to:

HELP Study
Centers for Disease Control and Prevention
4770 Buford Highway, MS F-40
Atlanta, GA 30341

If you have any questions, please do not hesitate to contact the HELP Study Team at (770) 488-7225.

Sincerely,

Mary Jean Brown, ScD, RN, Chief
Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Emergency
and Environmental Health Services
Lead Poisoning Prevention Branch

Mark Moody, Administrator
Department of Health and Family Services
Division of Health Care Financing

Attachment 7

Medicaid Provider Reminder/Follow-up Letter

Medicaid Provider Reminder/Follow-up Letter

Date:

Dear Dr. _____:

Greetings! A few weeks ago you were mailed a brief questionnaire from Helping to End Lead Poisoning (HELP). This is a study conducted with the Lead Poisoning Prevention Branch of the Centers for Disease Control and Prevention's National Center for Environmental Health and the Wisconsin Department of Health and Family Services. If you have already completed and returned the questionnaire, thank you for your participation. If not, please remember that the questionnaire should take no more than 10 minutes of your time. The information that we receive from you will help to improve the lead testing rates for the children at highest risk for lead poisoning.

As a reminder, all the information you provide will be kept in a confidential manner. Participant names will not be linked to questionnaires and researchers will not know which participants filled out the questionnaires.

Your participation is very important to the success of this study and we hope that you choose to participate by completing this questionnaire.

When you complete the questionnaire, please return it in the self-addressed stamped envelope provided or mail it to:

HELP Study
Centers for Disease Control and Prevention
4770 Buford Highway, MS F-40
Atlanta, GA 30341

If you have any questions please do not hesitate to contact the HELP Study team at 770-488-7225.

Sincerely,

Mary Jean Brown, ScD, RN, Chief
Centers for Disease Control and Prevention
National Center for Environmental Health
Division of Emergency and Environmental Health Services
Lead Poisoning Prevention Branch

Attachment 8
Medicaid Provider Reminder Phone Call Script

Hi, this is _____ from Helping to End Lead Poisoning (HELP), and we are working on a study on blood lead testing with the Centers for Disease Control and Prevention. We sent you a questionnaire a few weeks ago, but we have not yet received a response.

We really need your help in learning how to improve lead poisoning testing rates. Blood lead testing is known to be an important component in reducing the harmful effects of lead poisoning. Children eligible for Medicaid are typically at a higher risk for lead poisoning as compared to their non-Medicaid counterparts. Your responses to 15 questions would be helpful for us to learn how to improve lead poisoning testing rates.

May we have a few minutes of your time to complete the questionnaire over the phone?

If yes: (Complete the questionnaire)

If No: Thank you for your time.

Answering Machine

Hi, this is _____. I am calling from the Helping to End Lead Poisoning study. A questionnaire was sent to you a few weeks ago. Your participation in this study is very important to us and we hope that you choose to participate. If you already completed and returned your questionnaire, thank you for your participation. If you have any questions about the study, please feel free to contact us at 770-488-7225. Thank you for your time.