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

Application for OMB Clearance

RESUBMISSION

Resubmitted by

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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 children enrolled in Medicaid 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). Additionally, the Lead Contamination Control Act of 1988 authorized the CDC to initiate program efforts to eliminate childhood lead poisoning in the United States. As a result of this Act, one of LPPB's primary responsibilities is to educate healthcare providers about childhood lead poisoning.

A.2. Purpose and Use of the Information

This study is considered exploratory research by the research team because information of this kind has not been collected in the past. The purpose of this data collection is to begin to assess healthcare providers' practices, barriers, and beliefs regarding testing children enrolled in Medicaid for lead poisoning. This study will focus on a specific sample of Medicaid providers in Wisconsin. Wisconsin was selected as the state in which to conduct the pilot due to their ability to access real time Medicaid data.

We know that 100 percent of children enrolled in Medicaid are supposed to have a blood lead screening at ages one and two years of age. However from published reports and state and local data matching we know that blood screening rates vary for children enrolled in Medicaid.

To date, funding for lead poisoning prevention services remains a critical issue for most state and local health departments. Gaining information on Medicaid provider practices, barriers, and beliefs is an important factor in CDC's determining what course of action and /or education and outreach strategies should be developed to increase blood lead testing of Medicaid enrolled children under age six. For this reason, descriptive, quantitative data are needed to identify and document current beliefs, practices and perceived barriers to blood lead testing. Thus, to collect this data, a mailed questionnaire (Attachment 2) developed by knowledgeable investigators will be sent to Wisconsin Medicaid providers. Participants are asked to answer questions about their childhood blood lead testing practices, barriers, and beliefs. Randomly sampled Medicaid providers in Wisconsin will participate through a mailed questionnaire process.

LPPB staff will use the information collected in this study 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 enrolled in Medicaid. Results will be disseminated through presentations at conferences and through a peer-reviewed publication. 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 instrument requires 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 practice, barriers, and beliefs regarding childhood blood lead testing. We could not locate any other studies that assess Medicaid providers' self-reported practices, beliefs and barriers to childhood blood lead testing. One recent journal article on blood lead screening, Feinberg & Cummings (2005), noted that there is a need to understand blood lead testing barriers and that further studies to determine why physicians fail to order blood lead tests should be done.

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

It is noted that health care providers, such as physicians, are considered a small business. The questions on the survey have been held to the absolute minimum required for the intended use of the data. It takes approximately 10 minutes to complete the survey.

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:

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A.9. Explanation of Any Payment or Gift to Respondents

CDC LPPB key chains will be given to the Medicaid providers 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. Participants for this study will be recruited from the Wisconsin Medicaid Office's Medicaid Provider directory. This list will be used to mail the questionnaires to the randomly sampled Medicaid providers.

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 Medicaid providers' practices, barriers, and beliefs regarding testing children enrolled in Medicaid 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 children enrolled in Medicaid or about their routine testing practices. Questions #2 and #3 on the survey may be considered sensitive (Attachment 2). Question #2 is being asked to assess whether the respondent feels (believes) that children enrolled in Medicaid 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 #3 is being asked to assess whether the respondent routinely tests a child enrolled in Medicaid for lead poisoning. In this question we are assessing their current blood lead testing practice on children enrolled in Medicaid. 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)	440	1	10/60	73
Targeted Medicaid Providers in Wisconsin (telephone follow-up): "Yes"	110	1	10/60	18
Targeted Medicaid Providers in Wisconsin (telephone follow-up): "No" or mailed.	550	1	2/60	18
Total	1100			109

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)	440	10/60	$67	$4913
Targeted Medicaid Providers in Wisconsin (telephone follow-up):"Yes"	110	10/60	$67	$1228
Targeted Medicaid Providers in Wisconsin (telephone follow-up):"No" no response via mail	550	2/60	$67	$1228
Total	1100			$7369

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 (1/4 time)	$10,000
Evaluation Specialist (1/4 time)	$7,500
Epidemiologist (1/4 time)	$7,500
Printing	$1,600
Mailing	$500
Up-front Incentives	$400
Total	$27,500

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 one follow up mailing. 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 exploratory research. In order to determine why blood lead testing rates for children enrolled in Medicaid vary, a select sample of Medicaid providers in the State of Wisconsin will be surveyed. Questionnaires will be mailed to a random sample of Medicaid providers who 1) are one of the 7 provider types (section B) and 2) provide care to at least 50 or more children enrolled in Medicaid annually. The questionnaires will be sent from and returned to the CDC LPPB in Atlanta, Georgia. An incentive to complete the survey will be included in the questionnaire packet. 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 practices, barriers, and beliefs of Medicaid providers 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 a peer-reviewed publication. Participants may also request a summary of the major findings.

Project Time Schedule	
Activity	**Time Schedule**
Questionnaires mailed	3 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	6 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

Respondents will be randomly selected. The respondent universe consists of currently certified Medicaid providers, who 1) are in one of the 7 provider types (Pediatrics, General Practitioner, Family Medicine, Internal Medicine, Nurse Practitioner, Physician Assistant, and Screening Case Manager), and 2) see 50 or more Medicaid children (0-6 years of age) annually. We have chosen to survey only those Medicaid providers that are considered "primary care". In addition, we also chose to target our efforts on those Medicaid providers that see a large number of Medicaid patients. In this population for example, 73% of Medicaid enrolled children in the State of Wisconsin are seen by Medicaid providers that fit this criteria.

The approximate number of participants to which the questionnaire will be sent is 400. We are expecting a 50% response rate which would place the potential number of participating physicians at 200. We are expecting this response rate based on Cummings et. al. (2001) which found the average response rate for mailed physician surveys was 61% overall and was 52% for large-sample surveys. In order to have a significant power for the study we need 200 responses. We will obtain the Medicaid provider directory from the Wisconsin Medicaid Office.

B. 2. Procedures for the Collection of Information

This is exploratory research. Medicaid providers' will be surveyed to determine self-reported practices, beliefs, and barriers to childhood blood lead testing.

Questionnaires will be mailed to a random sample of Medicaid providers in the State of Wisconsin who 1) are in one of the 7 provider types (Pediatrics, General Practitioner, Family Medicine, Internal Medicine, Nurse Practitioner, Physician Assistant, and Screening Case Manager), and 2) see 50 or more Medicaid children (0-6 years of age) annually. The questionnaires will be sent from the CDC LPPB in Atlanta, Georgia. An incentive for completing the survey will be included in the questionnaire packet. 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 Medicaid provider'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, Evaluation Specialist, 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, non respondents 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. HELP study team members will call the non respondent during business hours to schedule a time to complete the questionnaire. Telephone numbers of the non respondents will be acquired from the Wisconsin Medicaid Office. 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 50%.

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 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:

Taran Jefferies, Evaluation Specialist
National Center for Environmental Health, CDC. Phone: 770-488-3616, Email: bre3@cdc.gov

Jaime Raymond, Epidemiologist
National Center for Environmental Health, CDC. Phone: 770-488-3616, Email: zvu0@cdc.gov

Curtis Blanton, Statistician
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Jeffrey Havlena, Surveillance Manager
Wisconsin Department of Health and Family Services
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CDC Investigator:
Principal Investigator (PI): Nikki Walker, MPH, 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.
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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 & Approval for Continuation
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)

TITLE III - GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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

Form Approved
OMB no. 0920-xxxx
Expiration Date: xx/xx/xx

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 age 6 years and younger enrolled in Medicaid?

1. Yes
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 (770-488-7225) to have your name removed from the list of eligible participants.

2. Do you feel that the children enrolled in Medicaid you provide for are:

a. more at risk for lead poisoning than other children?
b. at the same risk for lead poisoning as other children?
c. less at risk for lead poisoning than other children?

3. How often do you test a child enrolled in Medicaid for lead poisoning at a HealthCheck visit?

a. Always → **Please skip to question #6**
b. Sometimes
c. Rarely
d. Never

4. If you do not test all children enrolled in Medicaid, how do you determine whether or not to test a child for lead poisoning at a HealthCheck visit? Select all that apply.

1. Parents or office staff complete a standardized risk assessment questionnaire designed to identify children at greater risk of lead exposure
2. I ask questions about possible lead exposures during the visit
3. Parent expresses a concern about lead poisoning
4. I never test children for lead
5. Other (please specify)_____

5. If you do not test all children enrolled in Medicaid, please indicate to what extent the following factors prevent or pose barriers to you in obtaining blood lead tests. Darken the appropriate circle where 1=major factor; 2=somewhat of a factor; 3=minor factor; 4=not a factor at all, NS=not sure

(For formatting purposes only—each category will be reiterated above the column).....MF..SF..mF..NF..NS

a. The prevalence of venous lead levels ≥ 10µg/dL is low in my practice……..…1…2…3…4…NS
b. Interventions available for children with lead levels 10-19 µg/dL are ineffective…….1…2…3…4…NS
c. Parents report that their child has had a blood lead test done elsewhere…….....…1…2…3…4…NS
d. My risk assessment of the patients indicates that they are at low risk for lead exposure…….. 1…2…3…4…NS
e. Medicaid does not adequately reimburse for blood lead tests……..……...……1…2…3…4…NS
f. I order a blood lead test, but child fails to appear for appointment at the lab….....1…2…3…4…NS
g. There is not enough time during the HealthCheck visit to test blood lead levels……...1…2…3…4…NS
h. There are other issues that are more important to review with parents……..……1…2…3…4…NS
i. Parents refuse to have their child tested…….……..…1…2…3…4…NS

Please list any additional factors that prevent or pose barriers to you in obtaining blood lead tests_____

_____

_____

6. At what age(s) do you perform blood lead testing for children enrolled in Medicaid in your practice? <u>Select all that apply.</u>

a. I do not routinely order blood lead tests → **<u>Please skip to Question 10</u>**
b. Around the age of 6 months
c. Around the age of 12 months
d. Around the age of 18 months
e. Around the age of 24 months
f. Between 3-6 years with no test documented
g. At any time exposure may have occurred
h. Other (please specify)_____

7. What method(s) do you use to collect HealthCheck blood lead samples from children enrolled in Medicaid? <u>Please select your primary and secondary methods as applicable.</u>

	Primary	Secondary
a. Fingerstick sample into a microcontainer…….…..…….	1	2
b. Fingerstick sample on filter paper……...……..…….	1	2
c. Venipuncture…….…….…….……	1	2
d. Other (please specify)_____....……	1	2

8. Where do children enrolled in Medicaid have their HealthCheck blood lead sample drawn? <u>Please select the primary and secondary location as applicable.</u>

	Primary	Secondary
a. At the clinic during the examination…….…..……	1	2
b. At a laboratory in the same building or office complex as the clinic…	1	2
c. At a laboratory in another building……..…..……..……	1	2
d. At their WIC clinic…….…….....……	1	2
e. Other (please specify)_____. …….	1	2

9. What would be an incentive to you to draw all HealthCheck blood lead samples at your clinic? <u>Please make specific suggestions below.</u>

_____

_____

_____

_____

_____

10. Please indicate to what extent the following influence your current lead testing practices, where 1=very much; 2=somewhat; 3=a little; 4=not at all.

(For formatting purposes only—each category will be reiterated above the column)

VM..S..L…NaA

a. Journal article……..……..……1…2…3…4
b. Opinion of colleague(s)……. …..…...…1…2…3…4
c. Your own experience…….…..……1…2…3…4
d. CDC recommendations……..…..……1…2…3…4
e. The extent of lead poisoning in my community…..……1…2…3…4
f. Parental demand……..…..……1…2…3…4
g. Federal law……..…...…1…2…3…4
h. Local or state lead testing guidelines…….……1…2…3…4
i. Media coverage……..……1…2…3…4
j. Other (please specify)_____ …...1…2…3…4

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

1. Yes
2. No
a. Not sure

12. What is your gender?

1. Female
2. Male

13. Please indicate the type of certification or licensure you have.

1. Pediatrics
2. General Practice
3. Family Medicine
4. Internal Medicine
5. Nurse Practitioner
6. Physician Assistant
7. Screening Case Manager
8. Other (please identify)_____

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

1. Before 1971
2. 1971-1980
3. 1981-1990
4. 1991-2000
5. 2001 to present

15. How long have you been providing services to the Medicaid population?

_____

16. Please provide any additional comments or thoughts you would like to share_____

_____

_____

_____

_____

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 & Approval for Continuation

-----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

DATE: 3/14/2006

FROM: IRB Administrator
Human Research Protection Office
Office of Scientific Regulatory Services
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of Continuation of 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" (Expedited)

TO: MISHA WALKER [MNK2]
NCEH/EEHS

CDC's IRB "C" has reviewed and approved your request to continue protocol #4459 for the maximum allowable period of one year and it will expire on 1/23/2007. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), Category 4.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

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 1/23/2007.

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 Research Protection Office at (404) 639-4721 or e-mail: huma@cdc.gov.

Jennifer McCleary

cc:
Paula Braun
NCEH/ATSDR Human Subjects
Amy Sandul

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). The purpose of the study is to investigate the variance in blood lead testing rates of children enrolled in Medicaid by health care providers in the state of Wisconsin. 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. We hope to learn more about the full range of practices, barriers, and beliefs regarding lead poisoning testing of children enrolled in Medicaid among Wisconsin health care providers.

Why have you been asked to take part in this study?
We are distributing this mailed questionnaire to Wisconsin healthcare providers who provide care for children enrolled in the Medicaid program. You have been asked to be in this study because you were included in our selected sample of all Medicaid healthcare providers across the state.

What will you be asked to do?
You will be asked to complete a mailed, multiple-choice questionnaire. We estimate that the questionnaire will take about 10 minutes of your time to complete. Your participation is voluntary and for this one time only. We will ask you various questions regarding your lead poisoning testing practices and your opinions regarding lead testing. 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?
This research will provide insights into a better understanding of the full range of practices, barriers, and beliefs regarding lead poisoning testing among children enrolled in Medicaid. Increased understanding may have benefits for 1) your practice and 2) society by leading to the development of methods and strategies for effective blood lead testing.

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 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 Nikki Walker at phone number 770-488-7225. Her mailing address is 4770 Buford Highway NE, MS F-40, Atlanta, GA 30341. 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 at phone number (404) 639-4500. Their mailing address is 1600 Clifton Road, MS C-25, Atlanta, GA 30333.

Attachment 6

Questionnaire Introduction

Date:

Dear Healthcare Provider,

The Lead Poisoning Prevention Branch (LPPB) 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)." The purpose of the study is to investigate the variance in blood lead testing rates of children enrolled in Medicaid by health care providers in the state of Wisconsin.

We are distributing this mailed questionnaire to Wisconsin healthcare providers who provide care for children enrolled in the Medicaid program. We are asking you to complete the multiple-choice questionnaire found on the following pages. It is completely voluntary and should only take about 10 minutes of your time. Everyone's participation is important because it will help us learn more about the full range of practices, barriers, and beliefs regarding lead poisoning testing of children enrolled in Medicaid among Wisconsin health care providers.

Your participation is very important to the success of this study and we hope that you choose to participate. Please keep in mind that participant names will not be linked to questionnaires. Researchers will not know which answers belong to a specific participant. All results will be reported aggregately (not at the individual level).

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

Please return the completed questionnaire in the self-addressed stamped envelope. 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
Principal Investigator, WI Childhood Lead Poisoning Prevention Program
Department of Health and Family Services, Division of Health Care Financing

Tom Siegert, Co-Chair

Childhood Lead Poisoning Elimination Plan Committee
WI Division of Public Health
Bureau of Environmental and Occupational Health

Catherine Slota-Varma, MD, FEEP, Co-Chair
Childhood Lead Poisoning Elimination Plan Committee
Shoreview Pediatrics

Attachment 7

Medicaid Provider Reminder/Follow-up Letter

Date:

Dear _____:

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 take about 10 minutes now to complete the enclosed questionnaire. The information that we receive from you will help us learn more about the full range of practices, barriers, and beliefs regarding lead poisoning testing among Wisconsin children enrolled in Medicaid.

As a reminder, all the information you provide will be kept in a confidential manner. Participant names will not be linked to questionnaires. Researchers will not know which answers belong to a specific participant. All results will be reported aggregately (not at the individual level).

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

Please return the completed questionnare in the self-addressed stamped envelope. If you have any questions, please do not hesitate to contact the HELP Study Team at (770) 488-7225.

Sincerely,

Nikki Walker, M.P.H., Primary Investigator
HELP Study
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 from you.

We really need your help in learning more about current health care provider practices, barriers and beliefs regarding lead poisoning testing. Blood lead testing is known to be an important component in reducing the harmful effects of lead poisoning. Your responses would be helpful for us to learn about the full range of practices, barriers and beliefs regarding lead poisoning testing across Wisconsin.

There are 16 questions. 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 Nikki Walker at 770-488-7225. Thank you for your time.