(E) Annual Re-Certification by Children's Hospitals To Maintain Eligibility Status in 340B Drug Pricing Program

Children's hospitals have an ongoing responsibility to immediately notify OPA in the event of any change in eligibility for the 340B Drug Pricing Program. No less than on an annual basis, children's hospitals will need to demonstrate continued maintenance of the required disproportionate share adjustment percentage or disproportionate patient percentage. OPA will provide additional guidance as it gains experience and develops its plans to annually certify covered entities. To the extent that OPA is able to obtain periodic documentation of such data similar to that provided by CMS with respect to DSHs, it may notify the covered entity that such information need not be provided.

(F) Eligibility for Discounts Back to February 8, 2006

Section 6004 of the DRA indicates that the amendment authorizing entry of children's hospitals into the 340B Program ''shall apply to drugs purchased on or after the date of the enactment of this Act.'' The DRA provision was enacted on February 8, 2006. Therefore, once children's hospitals are admitted to the 340B Program and listed on the Covered Entity Database, they are eligible for 340B drug pricing back to February 8, 2006. However, a children's hospital will be eligible for such retroactive discounts only to the extent that it has satisfied all requirements for participation in the 340B program back to the date discounts are requested.

Children's hospitals may request retroactive discounts (discounts, rebates, or account credit) directly from pharmaceutical manufacturers for covered outpatient drugs when all the following conditions are satisfied:

(1) The children's hospital is listed on the 340B Covered Entity Database as eligible to purchase under 340B within one year of publication of this notice.

(2) The children's hospital sent a request in writing to each manufacturer of the drug(s) for which retroactive discounts are sought within 30 days of the children's hospital having been listed as eligible to purchase under 340B on the 340B Covered Entity Database;

(3) The covered outpatient drugs must have been purchased on or after February 8, 2006;

(4) The covered outpatient drugs must not have generated Medicaid rebates (the children's hospital must have appropriate documentation to demonstrate this);

(5) The covered outpatient drugs must not have been sold or transferred to a person who was not a patient of the children's hospital; and

(6) The covered outpatient drugs must have been purchased on or after the date on which the children's hospital satisfied all requirements for participation in the 340B Program as outlined in section (D) of this notice.

In order to satisfy the last condition listed above, a children's hospital must be able to demonstrate, at a minimum, that as required by section 340B(a)(4)(L)(iii) of the Public Health Service Act, the children's hospital did not have a group purchasing agreement for covered outpatient drugs and satisfied the requirements of section 340B(a)(4)(L)(i) and 340B(a)(4)(L)(ii) at the time the covered outpatient drugs for which rebates are requested were purchased. Participation in a GPO for any covered outpatient drugs would disqualify a children's hospital for retroactive rebates during any quarter that the children's hospital purchased any covered outpatient drug through a GPO or other group purchasing arrangement. Consistent with section 340B(a)(5)(C) of the Public Health Service Act, children's hospitals must have auditable records that support claims for retroactive discounts and permit the Government or manufacturers to audit those records (in accordance with procedures established by the Secretary relating to the number scope and duration of such audits (61 FR 65406)).

In fulfilling the conditions listed above, any children's hospital that believes it is entitled to retroactive discounts may preserve its rights by sending manufacturers a letter requesting such refunds, explaining how they meet the requirements in this notice, and providing adequate documentation of purchases within 30 days being listed on the 340B Covered Entity Database as eligible. Such children's hospitals should engage in good faith efforts to resolve any disputes with manufacturers. To the extent they are unable to resolve disputes and wish to pursue further involvement with the OPA, they are encouraged to follow the guidance on the dispute resolution process as described in the **Federal Register** (61 FR 65406).

Dated: August 26, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–21109 Filed 8–31–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Health IT Community Tracking Study 2009.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on June 30th, 2009 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 1, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrg.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Health IT Community Tracking Study 2009

Electronic prescribing (e-prescribing) is a central focus of efforts to promote health information technology (IT) and is of particular interest to AHRQ because of its potential to improve patient safety by reducing medication errors. Despite many public- and private-sector initiatives to support e-prescribing, to date, physician adoption and use has been limited (Friedman, Schueth and Bell 2009). Recently, Section 132 of the Medicare Improvements for Patients and

Providers Act of 2008 (MIPPA), Public Law 110–275, authorized a new incentive program for eligible individual providers who are successful e-prescribers. In addition, Section 4101 of the American Recovery and Reinvestment Act of 2009 (ARRA), Public Law 111–5, provides incentives for meaningful use of electronic health record technology, which includes the use of e-prescribing.

The potential gains from e-prescribing assume that prescribers and pharmacists have access to the required features and use them. Limited research on the topic suggests, however, that not all e-prescribing systems currently have the full range of e-prescribing features required under MIPPA; that even when the features are available, physician practices face barriers to implementing them effectively; and even when they are implemented at the practice level, physicians may not use them. For example, in a small, exploratory qualitative study by Grossman, *et al.* (2005), physicians did not routinely have access to patient medication histories or formulary data for a significant portion of their patients and when they did, physicians often did not use the information, instead continuing to rely on patients for medication history and pharmacists to identify formulary issues. Several studies have identified that IT system limitations, workflow and training issues, and real or perceived regulatory barriers present obstacles in both the physician and pharmacy settings to electronic transmission of prescriptions (Grossman *et al.* 2007; NORC 2007; Rupp and Warholak 2008; Warholak and Rupp 2009).

AHRQ proposes to conduct a qualitative research study designed to help build knowledge on how the e-prescribing features required under MIPPA are actually being implemented and used by physicians and pharmacies in 12 nationally representative communities. These communities have been studied longitudinally since the mid-1990s as part of the Center for Studying Health System Change (HSC) Community Tracking Study (CTS) (Center for Studying Health System Change 2007). This qualitative study will collect data from physician practices and pharmacies that are using electronic transmission of prescriptions to allow a focus on both the facilitators of and barriers to this critical aspect of e-prescribing. The study will be the first to ask questions of physician practices and pharmacies in the same communities on the same topics, providing a much more complete picture of e-prescribing implementation. For example, in addition to gaining physician and pharmacy perspectives on electronic transmission, the study will explore how physician practices use patient formulary data and how pharmacies perceive changes in the communication with physician practices around formulary issues with e-prescribing.

Information collected by this study will inform strategies to promote the adoption and effective use of e-prescribing being developed by AHRQ and other Department of Health and Human Services agencies, including the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health IT, as well as State and local governments and private health care organizations. In particular, while physician adoption has been the focus of most policy efforts, findings from the study can help identify and shape strategies to promote more effective implementation of e-prescribing in retail and mail-order pharmacies. This work will be conducted by AHRQ's contractor, the Center for Studying Health System Change (HSC), under contract number 290–05–0007–03. This study is being conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and systems for the delivery of such care, including activities with respect to health care technologies, facilities and equipment, 42 U.S.C. 299a(a)(5).

Method of Collection

The study will use qualitative methods, including telephone interviews with physician practices and pharmacies, as well as State pharmacy associations, IT vendors and other e-prescribing experts. Using semi-structured interview protocols, the following specific research questions will be addressed to provide an in-depth look at unexplored barriers to effective e-prescribing use in physician practices and pharmacies, including:

☐ How are physicians using third-party information in making prescribing decisions, including patient medication history, generic drug information, and patient-specific formulary data?

☐ How are physician practices and retail and mail-order pharmacies using e-prescribing systems to communicate electronically with each other?

☐ What are the most common reasons that physician practices and pharmacies communicate about prescriptions generated by physician e-prescribing systems (regardless of how they were sent)?

☐ What are the facilitators of and challenges to implementing e-prescribing features that support physician access to third-party information in making prescribing decisions and features that support electronic communication between physician practices and pharmacies?

☐ What are the perceived effects of having access to e-prescribing features that support physician access to third-party information in making prescribing decisions and features that support electronic communication between physician practices and pharmacies on physician practice and pharmacy operations, physician prescribing behavior and patient outcomes?

☐ What are the implications for policy efforts to promote e-prescribing?

Estimated Annual Respondent Burden

Interviews will be conducted at a total of 110 organizations over the two years of this project. Within each of the 24 participating physician practices (12 annually), two interviews will be conducted: One with the medical director or physician-user best able to describe practice processes for e-prescribing, who will provide a clinical perspective (Interview Protocol 2), and a second with an IT administrator or office manager, who can provide a technical and operational perspective (Interview Protocol 1). The other 86 organizations will each have only one interview, for a total of 43 additional interviews annually. Eight different organization-specific interview protocols have been developed, with response times ranging from 30 minutes to 1 hour.

Exhibit 1 shows the estimated annual burden hours for each organization's time to participate in this research. The total annual burden is estimated to be 57 hours.

Exhibit 2 shows the estimated annual cost burden associated with the organizations' time to participate in this research. The total annual burden is estimated to be $3,004.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of organizations*	Number of responses per organization	Hours per response	Total burden hours
Interview Protocol 1—Physician Practice IT administrator or Office Manager	12	1	30/60	6
Interview Protocol 2—Physician Practice Medical Director or Physician User	12	1	45/60	9
Interview Protocol 3—Pharmacy Pharmacist-In-Charge	28	1	1	28
Interview Protocol 4—State Pharmacy Association Representative	6	1	1	6
Interview Protocol 5—Pharmacy IT Vendor Representative	1	1	1	1
Interview Protocol 6—E-prescribing System Vendor Representative	3	1	1	3
Interview Protocol 7—E-prescribing Connectivity and Content Vendor Representatives	1	3	3	1
Interview Protocol 8—Other E-prescribing Experts	2	1	30/60	1
Total	67	NA	NA	57

* The estimated total number of unique organizations participating in each year of the study is 55 since Interview Protocols 1 and 2 will both be administered to respondents in physician practices.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of organizations*	Total burden hours	Average hourly wage rate**	Total cost burden
Interview Protocol 1—Physician Practice IT Administrator or Office Manager	12	6	$32.62	$196
Interview Protocol 2—Physician Practice Medical Director or Physician User	12	9	80.42	724
Interview Protocol 3—Pharmacy Pharmacist-In-Charge	28	28	48.09	1,347
Interview Protocol 4—State Pharmacy Association Representative	6	6	49.89	299
Interview Protocol 5—Pharmacy IT Vendor Representative	1	1	54.75	55
Interview Protocol 6—E-prescribing System Vendor Representative	3	3	54.75	164
Interview Protocol 7—E-prescribing Connectivity and Content Vendor Representatives	3	3	54.75	164
Interview Protocol 8—Other E-prescribing Experts	2	1	54.75	55
Total	67	57	NA	3,004

* The estimated total number of unique organizations participating in each year of the study is 55 since Interview Protocols 1 and 2 will both be administered to respondents in physician practices.

** Wage rates were calculated using the mean hourly wage from the U.S. Department of Labor, Bureau of Labor Statistics, May 2007 National Occupational Employment and Wage Estimates for the United States, Occupational Employment Statistics (OES), Washington, DC (Feb. 2009), *http://www.bls.gov/oes/2007/may/oes_nat.htm* (accessed April 2009). Wage rate for Interview Protocol 3—Pharmacy Pharmacist-In-Charge reflects the weighted average for retail and mail order pharmacists ($47.58 per hour) and pharmacy chain representatives ($54.75 per hour).

Estimated Annual Costs to the Federal Government

The estimated total cost to the Federal Government for this project is $374,635 over a two-year period from February 2, 2009 to February 1, 2010. The estimated average annual cost is $187,318. Exhibit 3 provides a breakdown of the estimated total and average annual costs by category.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUAL COST* TO THE FEDERAL GOVERNMENT

Cost component	Total cost	Annualized cost
Project Development and Project Management	$87,783	$43,892
Data Collection Activities	141,048	70,524
Data Analysis	55,884	27,942
Publication and Dissemination of Results	89,920	44,960
Total	374,635	187,318

* Costs are fully loaded including overhead and G&A.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent

request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 19, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–20854 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–09–09BU]

Agency Forms Undergoing Paperwork Reduction Act Review

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

Proposed Project

National Adult Tobacco Survey (NATS)—New—Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Tobacco use remains the leading preventable cause of disease and death in the United States. Although the prevalence of current smoking among adults decreased significantly from 1998 to 2007 in 44 states, the District of Columbia, and Puerto Rico, only one State and one territory have met Healthy People 2010 targets for reducing adult smoking prevalence to 12%, and six States have shown no substantial changes in prevalence after controlling for age, sex, and race/ethnicity.

CDC proposes to conduct the National Adult Tobacco Survey (NATS) in 2009–2010 to help evaluate and improve the effectiveness of CDC's National Tobacco Control Program (NTCP). The NATS will be a one-time, stratified, random-digit dialed telephone survey of non-institutionalized adults 18 years of age and older. Essential information will be collected on key indicators from each of the NTCP's four goal areas: (1) The prevention of initiation of tobacco use among young people, (2) the elimination of nonsmokers' exposure to secondhand smoke, (3) the promotion of quitting among adults and young people, and (4) the elimination of tobacco-related disparities.

In order to yield results that are representative and comparable at both national and state levels, information will be collected from approximately 1,863 land-line telephone users in each state and the District of Columbia. In addition, a total of approximately 3,000 interviews will be conducted from a national sample of cell phone users to include the growing population of households that rely exclusively on cell phones. All interviews will be conducted using computer-assisted telephone interview (CATI) methodology.

Survey results will be used to develop estimates of tobacco use at the national level by gender and race/ethnicity and to evaluate comprehensive Tobacco Control Programs. Study results will have significant implications for the development of policies and programs aimed at preventing or reducing tobacco use. There are no costs to respondents except their time. The estimated annualized burden hours are 38,303.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Adults ages 18 or older	Screener for land-line users (pp 11–18 of the NATS)	166,273	1	2/60
	Screener for cell phone users (pp 2–11 of the NATS)	5,400	1	1/60
	National Adult Tobacco Survey (pp 19–92 of the NATS)—landline.	95,013	1	20/60
	National Adult Tobacco Survey (pp 19–92 of the NATS)—cell phone.	3,000	1	20/60

Dated: August 26, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–21043 Filed 8–31–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-09–0730]

Agency Forms Undergoing Paperwork; Reduction Act Review

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

Proposed Project

Evaluation of the Effectiveness of the Smoke Alarm Installation and Fire Safety Education (SAIFE) Program [OMB No. 0920–0730 Exp. 9/30/2009]—Extension—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).