to complete the survey and two-follow-up assessments. Therefore, over three years 2400 students will undergo an intake assessment, of whom we will recruit 1800 students into the study (300 per year from intervention schools and 300 per year from control schools), of whom we anticipate 1200 will have complete data.

There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Middle and High School Students	Intake assessment	800	1	15/60	200
	Baseline Survey	600	1	1	600
	Completion Survey	400	1	1	400
	Follow-up Survey 1	400	1	1	400
	Follow-up Survey 2	400	1	1	400
Total					2000

Dated: July 24, 2009.

Marilyn S Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–18604 Filed 8–3–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Intervention Trials To Retain HIV-Positive Patients in Medical Care: (New)

The purpose of this project is to develop, implement, and test the efficacy of an intervention designed to increase client appointment attendance among patients at risk of missing scheduled appointments at HIV clinics. This project is a collaboration between the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and six university-affiliated HIV clinics in the United States. The proposed intervention will be implemented in two phases. Phase 1 is a clinic-wide intervention that includes the following components: a theme slogan for the intervention, brochures, posters with messages to patients, brief verbal retention in care messages from providers to patients, buttons printed with the theme of the intervention worn by providers, and appointment reminder cards with information on how to cancel appointments. All clinic patients will receive the Phase 1 intervention. Phase 2 of the project is a three-arm randomized trial in which 300 patients in each of the six participating sites will be enrolled and randomly assigned to one of three study arms. In Arm 1 (control arm), patients (n=100) will receive the clinic-wide intervention only. Patients (n=100) assigned to Arm 2 (intervention arm) will continue to receive the clinic-wide intervention plus a comprehensive client-centered intervention from two trained interventionists. The remaining 100 patients will be assigned to Arm 3 and will receive the clinic-wide intervention plus a brief client-centered intervention.

The efficacy of the intervention will be assessed through data collection efforts tailored to each phase of the intervention. Phase 1 uses a pre-post comparison of clinic attendance rates before and during a clinic-wide intervention. Specifically, in Phase 1, the attendance rate for HIV primary care is currently being assessed via electronic medical records during the 12-month period before the clinic-wide intervention begins. This pre-intervention assessment is being collected for all patients who had at least one HIV primary care visit at the clinic during the preceding 12 months. This cohort of patients will be reassessed via electronic medical records during the 12-month intervention period. In addition, provider surveys will be administered quarterly during Phase 1 and semi-annually during Phase 2 to obtain information from primary care providers (MD, DO, nurse practitioner, physician assistant) about whether they talked to their patients about the importance of regular care. Patient exit interviews will be administered every other month to assess patient exposure to the theme slogan for the intervention and posters with messages to patients as well as receipt of brochures and brief verbal retention in care messages from clinicians and clinic staff that comprise the Phase 1 intervention.

In Phase 2, participants will be enrolled over a period of 4–9 months to allow flexibility for faster or slower enrollment in the clinics. It is anticipated that most clinics will complete their enrollment in approximately 6 months. On a daily basis, clinic staff or the study coordinator will generate a list of patients who meet eligibility criteria based on attendance history. The list will be given to the study coordinator who will approach patients to ask about their interest in being screened for eligibility in the study. When patients agree to be screened for eligibility, the study coordinator will administer an eligibility screener. Patients who are found to be eligible will be enrolled in the project and all enrollees will complete a baseline survey (that will take approximately 30 minutes) before being randomized to one of the two intervention arms or the control arm. No follow-up surveys will be collected. The survey will be administered in a private setting at the clinic using Audio Computer-Assisted Self-Interview (ACASI) in which respondents can read and listen via earphones to survey questions presented on the computer screen and respond directly into the computer.

Participants randomly assigned into the intervention arms will receive comprehensive or brief interventional services from two trained interventionists. The interventions will be delivered in face-to-face encounters as well as over the telephone and the first dose of the intervention will be delivered on the day the participant is enrolled into study. During the first face-to-face encounter, an interventionist will administer a retention risk screener. This screener is a clinical tool that will help identify attitudes, barriers, and unmet needs that might prevent a patient from staying in care. The screener contains three sections: (1) Attitudes and beliefs about HIV care and treatment, (2) barriers to consistent clinic attendance (e.g., transportation, child care, housing instability, scheduling problems, and lack of social support), and (3) recent drug/alcohol use and mental health. The information obtained from the risk screener will be used to tailor the interventions to each individual patient's needs. Because a patient's situation or needs may change over time, the screener will be re-administered to intervention arm participants at a minimum every 3–4 months during a clinic visit or other arranged face-to-face meetings outside of the clinic. In addition, the study coordinator will obtain contact/locator information for all participants enrolled in the intervention arm. Contact information will be updated as necessary by the intervention staff.

The response burden for the six participating sites and patients enrolled in the study is estimated as:

ESTIMATED ANNUALIZED BURDEN HOURS

Type of form by phase	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden (in hours)
Phase 1					
Primary Care Provider Survey	150	4	600	0.167	100
Clinic Staff Survey	270	4	1,080	0.167	180
Patient Exit Survey	1,800	1	1,800	0.033	60
.....					
Electronic data abstraction	6	4	24	40.0	960
Phase 1 Burden	2,226	.....	3,504	.....	1,300
Phase 2					
Primary Care Provider Survey	150	2	300	0.167	50
Clinic Staff Survey	270	2	540	0.167	90
Patient Exit Survey	1,800	1	1,800	0.033	60
Patient Eligibility Screener*	3,000	1	3,000	0.083	249
Patient Baseline Survey*	1,800	1	1,800	0.50	900
Retention Risk Screener	1,200	4	4,800	0.25	1,200
Retention Specialist/Patient Navigator Encounter	12	300	3,600	0.017	61
Contact/locator information	1,200	4	4,800	0.083	398
Electronic data abstraction	6	4	24	40.0	960
Phase 2	8,238	.....	20,664	.....	3,968
Total Burden	11,664	.....	24,168	.....	5,268

*Only administered one time during the entire project period.

Written comments and recommendations concerning this proposed information collection should be sent within 30 days of this notice to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for HRSA.

Dated: July 27, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–18524 Filed 8–3–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0277]

Authorization of Emergency Use of Certain In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations), one of which was amended, for certain in vitro diagnostic devices. FDA is issuing the Authorizations under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostics. The Authorizations follow the determination by the Acting Secretary of the Department of Health and Human Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain in vitro diagnostics, accompanied by emergency use information subject to the terms of any authorization issued under the act.