

attributable to stroke. As of 2001, the average stroke death rate for the Seven Core Stroke Belt States was significantly higher than the U.S. national average or that for the remaining 43 states and the District of Columbia (about 22 percent and 26 percent higher, respectively).

**Stroke Risk Factors:** Risk factors for stroke include high blood pressure, excess weight, and heart disorders such as atrial fibrillation, an irregular heart rhythm, or a large area of heart wall damage due to a heart attack. High cholesterol, smoking, significant carotid artery disease, markedly high red blood cell count, and sleep apnea are also risk factors. The risk of stroke increases with age, being over 25-times higher for persons 75 years and older, and over 11-times higher for persons 65 to 74 years-old, compared to persons 35 to 44 years of age. Men 75 years and older have a 16 percent higher risk of stroke compared to women. A history of a prior stroke or mini-stroke (transient ischemic attack, TIA) or a family history of stroke are associated with increased stroke risk. The presence of diabetes increases the risk of stroke by over 150 percent. The importance of risk factors is underscored by the fact that persons with a low risk profile for heart disease or stroke are almost 60 percent less likely to die prematurely. These persons are also estimated to live up to 9.5 years longer. Accordingly, clinical practice guidelines for early intervention exist and have been recently updated.

**The Demographic Disparity of Death from Stroke:** As of 2001, Latino/Hispanic persons had the lowest stroke death rate (44.9 deaths per 100,000, age-adjusted). Rates for non-Latino/Hispanic blacks, whites, and others were 74 percent, 25 percent and 29 percent higher, respectively. Lack of early clinical management of ischemic stroke increases the risk of disability and death.

**Hypertension Defined:** Adult hypertension is currently defined as present when systolic blood pressure is  $\geq 140$  mm Hg, or diastolic BP  $\geq 90$  mm Hg on multiple readings over several different days, or when a person is taking anti-hypertensive medication to control BP over time. Blood pressure normally varies over time. Accordingly, a high blood pressure reading does not always constitute hypertension in an individual; the time element is an important component of the diagnosis. This is why referral to care for formal assessment and management is recommended following detection of elevated BP during a screening event.

**Hypertension Is a Potent Stroke Risk Factor:** Hypertension is one of the most prevalent and powerful risk factors for

stroke. The risk of dying from stroke rises rapidly as blood pressure increases above 115/75 mm Hg. Stroke mortality doubles for every 20 mm Hg rise in systolic BP or for every 10 mm Hg rise in diastolic BP. Very importantly, the risk of stroke falls exponentially as high blood pressure is controlled to guideline-recommended levels in persons with hypertension. For this reason, the SBEI focuses on hypertension as the priority risk factor while facilitating activities that will also favorably impact other stroke risk factors. Hypertension is both preventable and treatable using a combination of lifestyle changes and medication.

**Hypertension Burden:** The public health, health care, and economic burdens of hypertension are substantial. Hypertension is the most common cardiovascular disease and the most common primary care clinical diagnosis in the U.S. It is estimated that not fewer than 50 million U.S. adults have hypertension. The burden of hypertension rises with age; over 80 percent of U.S. adults with hypertension are  $\geq 45$  years of age. A person with normal blood pressure at 55 years of age has a 90 percent risk of developing hypertension over their remaining lifetime. Health care costs for patients with hypertension and complications due to high blood pressure are estimated at \$109 billion for 1998 (over \$120 billion in U.S. 2002 dollars). About \$22 billion of the total estimate was spent for anti-hypertensive treatment alone (over \$24 billion in U.S. 2002 dollars). The average amount spent annually per person with a hypertensive condition was about \$3,787 and about \$4,180 in U.S. 2002 dollars when hypertensive complications and co-morbid conditions are included. Carving out complications and hypertensive co-morbidities yielded an estimated total 2004 cost of \$55.5 billion for hypertensive disease alone (at least \$1,110 per person for hypertension alone).

**Why Hypertension Prevention and Control and Key Goals:** It is estimated that almost 50,000 strokes could be prevented and more than 28,000 U.S. lives saved each year if about 90 percent of persons with hypertension had their blood pressure controlled to guideline-recommended levels. Intensified hypertension control was very cost-effective in a recent cost-effectiveness analysis of patients with type 2 diabetes. Nationally, in spite of notable successes over the years, only about 59 percent of adults with hypertension were being treated and only about 34 percent of adults with hypertension had their blood pressure controlled to guideline-

recommended levels in 1999–2000. Mean high blood pressure control rates for the year 2002 for commercial health plans, Medicare and Medicaid were 58.4 percent, 56.9 percent and 53.4 percent, respectively. These values represent significant improvements over year 2000 values and thus, serve as a basis for encouragement toward continued performance improvement. A recent analysis of data from the third National Health and Nutrition Examination Survey (NHANES III; 1988–1994) indicates that although there were some differences in health care access and utilization, about 92 percent of adults with uncontrolled hypertension reported having health insurance and 86 percent of them had a usual source of care. It was also found that U.S. adults with hypertension not controlled to guideline-recommended levels reported an average of over four visits per year to physicians. About 75 percent of U.S. adults in the NHANES III survey who were not aware that they had hypertension, had their blood pressure checked by a health professional at some time within the prior 12 months.

### 3. Healthy People 2010

The PHS is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity announced in January 2000 to eliminate health disparities and improve years and quality of life. More information may be found on the Healthy People 2010 Web site: <http://www.healthypeople.gov>. Copies of the *Healthy People 2010: Volumes I and II* can be purchased by calling (202) 512-1800 (cost \$70.00 for printed version; \$20.00 for CD-ROM). Another reference is the *Healthy People 2000 Final Review 2001*. For one free copy of *Healthy People 2010*, contact: The National Center for Health Statistics (NCHS), Division of Data Services, 3311 Toledo Road, Hyattsville, MD 20782; or, telephone (301) 458-4636. Ask for DHHS Publication No. (PHS) 99-1256. This document may also be downloaded from the <http://www.healthypeople.gov>.

### 4. Resources

The following are Web sites from various Federal and non-Federal sources that may serve as resources as you develop your proposals related to stroke and/or high blood pressure prevention and control:

Agency for Healthcare Research & Quality

Put Prevention Into Practice, <http://www.ahrq.gov/clinic/ppipix.htm>.

Guide to Clinical Preventive Services, Chapters 19 & 21, <http://hstat.nlm.nih.gov/hq>.

Centers for Disease Control and Prevention

Guide to Community Preventive Services, <http://www.thecommunityguide.org>.

Promising Practices in Chronic Disease Prevention and Control, Chapter on Achieving a Heart-Healthy and Stroke-Free Nation, [http://www.cdc.gov/nccdphp/promising\\_practices/index.htm](http://www.cdc.gov/nccdphp/promising_practices/index.htm).

Overweight and Obesity, <http://www.cdc.gov/nccdphp/dnpa/obesity/index.htm>.

Centers for Excellence—Exemplary State Programs, [http://www.cdc.gov/nccdphp/exemplary/heart\\_disease.htm](http://www.cdc.gov/nccdphp/exemplary/heart_disease.htm) and <http://www.cdc.gov/nccdphp/exemplary/diabetes.htm>.

State Heart Disease and Stroke Prevention Program <http://www.cdc.gov/cvh/stateprogram.htm>.

State-Based Nutrition and Physical Activity Program; Obesity; 5 A-Day; Active Community Environments; Kids Walk to School; Physical Activity, <http://www.cdc.gov/nccdphp/dnpa>.

Atlas of Stroke Mortality (county-level data), Cardiovascular Health Program, CDC, <http://www.cdc.gov/cvh>.

WISEWOMAN (Well Integrated Screening & Evaluation for Women Across the Nation): Screening and Lifestyle Interventions for Many Low-Income, Uninsured Women, <http://www.cdc.gov/wisewoman>.

Surgeon General's Report on Physical Activity, <http://www.cdc.gov/nccdphp/sgr/sgr.htm>.

National Health and Nutrition Examination Survey, <http://www.cdc.gov/nchs/nhanes.htm>.

Behavioral Risk Factor Surveillance System—State, city and county data, <http://apps.nccd.cdc.gov/brfss/index.asp>.

Centers for Medicare & Medicaid Services

Quality Initiatives (main page summary), <http://cms.hhs.gov/quality/>.

Quality Fact, Sheet <http://cms.hhs.gov/quality/QualityFactSheet.pdf>.

Hospital Quality Initiative (National Voluntary Hospital Reporting Initiative), <http://cms.hhs.gov/quality/hospital/>.

Medicaid Quality in Home and Community Based Services, <http://cms.hhs.gov/medicaid/waivers/quality.asp>.

Quality in Managed Care, <http://cms.hhs.gov/healthplans/quality/>.

Demonstration Projects and Evaluation Reports, <http://cms.hhs.gov/researchers/demos/>.

Medicare Physician Group Practice Demonstration, <http://cms.hhs.gov/researchers/demos/PGP.asp>.

CMS Research Activities: The Active Projects Report, 2003 Edition, Theme 7: Outcomes, Quality and Performance, <http://cms.hhs.gov/researchers/projects/apr/> (complete report), <http://cms.hhs.gov/researchers/projects/APR/2003/theme7.pdf>.

Quality Improvement Organizations (QIOs), <http://cms.hhs.gov/qio/>.

Statistics and Data, <http://cms.hhs.gov/researchers/>.

Health Resources and Services Administration

Find a Health Center; people looking for low cost health care, <http://bphc.hrsa.gov/>.

Area Health Education Centers; Health Education Training Centers, <http://bhpr.hrsa.gov/interdisciplinary/hetc.html>.

Indian Health Service

IHS National Diabetes Program; Diabetes topics; Nutrition topics; Pediatric Height and Weight Study; IHS Best Practice Model; Type 2 Diabetes in Youth; School Health-Physical Activity and Nutrition; Pathways; Cardiovascular Disease, [http://www.ihs.gov/MedicalPrograms/Medical\\_index.asp](http://www.ihs.gov/MedicalPrograms/Medical_index.asp).

National Institutes of Health

Evidence-Based Health Information for the Public, <http://medlineplus.gov>.  
NIDA Nicotine Information Page, <http://www.drugabuse.gov/drugpages/nicotine.html>.

Evidence-Based Approaches for Implementation of 5 A Day for Better Health, [http://dccps.nci.nih.gov/5ad\\_6\\_eval.html](http://dccps.nci.nih.gov/5ad_6_eval.html).

Obesity Education Initiative, [http://www.nhlbi.nih.gov/health/public/heart/obesity/lose\\_wt/index.htm](http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/index.htm).

Hearts N' Parks, [http://www.nhlbi.nih.gov/health/prof/heart/obesity/hrt\\_n\\_pk/index.htm](http://www.nhlbi.nih.gov/health/prof/heart/obesity/hrt_n_pk/index.htm).

Heart Healthy Recipes, [http://www.nhlbi.nih.gov/health/public/heart/obesity/lose\\_wt/recipes.htm](http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/recipes.htm).

National High Blood Pressure Education Program, <http://www.nhlbi.nih.gov/hbp/index.html>.

National Cholesterol Education Program, <http://www.nhlbi.nih.gov/chd/index.htm>.

Information for Patients & General Public, <http://www.nhlbi.nih.gov/health/public/heart/index.htm>.

Enhanced Dissemination & Utilization Centers (EDUCs) in communities, <http://hin.nhlbi.nih.gov/educs/awardees.htm>.

The Heart Truth Campaign, <http://www.nhlbi.nih.gov/health/hearttruth/index.htm>.

Act in Time to Heart Attack Signs, <http://www.nhlbi.nih.gov/actintime/index.htm>.

Healthy People 2010 Cardiovascular Gateway, [http://hin.nhlbi.nih.gov/cvd\\_frameset.htm](http://hin.nhlbi.nih.gov/cvd_frameset.htm).

Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report, [http://www.nhlbi.nih.gov/guidelines/obesity/ob\\_home.htm](http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm).

Body Mass Index Calculator, <http://www.nhlbisupport.com/bmi/bmicalc.htm>.

National Diabetes Education Program; Small Steps, Big Rewards—Prevent Type 2 Diabetes, <http://www.ndep.nih.gov>.

Diabetes Research and Training Centers Demonstration and Education Divisions; The Pima Indians—Pathfinders for Health; Diabetes Prevention Program Prevention Trial—Type 1 (DPT-1); Look Ahead (Action in Health for Diabetes), <http://www.niddk.nih.gov/patient/show/lookahead.htm>.

Stroke Awareness, [http://www.ninds.nih.gov/news\\_and\\_events/pressrelease\\_may\\_stroke\\_050801.htm](http://www.ninds.nih.gov/news_and_events/pressrelease_may_stroke_050801.htm).

Weight Control Information Network, <http://www.niddk.nih.gov/health/nutrit/win.htm>.

Exercise: A Guide from the National Institute on Aging, <http://nia.nih.gov/exercisebook/>.

Office of the Secretary

HealthierUS, <http://www.healthierus.gov/>, <http://www.whitehouse.gov/infocus/fitness/>.

Healthy People 2010, <http://www.health.gov/healthypeople/document/html>.

Best Practices Initiative—Comprehensive Diabetes Control Program, <http://www.osophs.dhhs.gov/ophs/BestPractice/MI.htm>.

Nutrition Guidelines (Developed by HHS and United States Department of Agriculture), <http://www.health.gov/dietaryguidelines/>.

The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity, <http://www.surgeongeneral.gov/topics/obesity>.

Girls and Obesity Initiative, <http://www.4woman.gov/owh/education.htm>.

Non-Federal Resources

Tri-state Stroke Network, <http://www.tristatestrokenetwork.org>.

State Heart Disease and Stroke Prevention Programs, <http://www.cdc.gov/cvh/stateprogram.htm>.

American Heart Association, <http://www.americanheart.org>.

American Heart Association's Guide for Community-Wide Cardiovascular

Health, <http://www.americanheart.org/presenter.jhtml?identifier=3008344>.

American Stroke Association, <http://www.strokeassociation.org>.

Comprehensive resource, for patients and families, <http://www.medlineplus.org>.

Health Disparities Collaborative, <http://www.healthdisparities.net/>.

National Stroke Association, <http://www.stroke.org>.

National training program using community mobilization model, <http://www.diabetestodayntc.org>.

University of Michigan's Mfit Community Nutrition Program, <http://www.mfitnutrition.com/supermarketprogram.asp>.

Web-based training program on how to provide tobacco cessation counseling, <http://oralhealth.dent.umich.edu/VODI/html/index.html>.

Writing in plain language, <http://www.plainlanguage.gov/handbook/index.htm>.

#### Evaluation and Logic Models

CDC Office on Smoking and Health, [http://www.cdc.gov/tobacco/evaluation\\_manual/app\\_b.html](http://www.cdc.gov/tobacco/evaluation_manual/app_b.html).

CDC Division of Nutrition and Physical Activity, <http://www.cdc.gov/nccdphp/dnpa/physical/handbook/step2.htm#logic>.

Kellogg Foundation Logic Model Development Guide (under "Tools", "Evaluation"), <http://www.wkkf.org/>.

Promising Practices in Chronic Disease Prevention and Control: A Public Health Framework for Action, [http://www.cdc.gov/nccdphp/promising\\_practices/pdfs/Heart.pdf](http://www.cdc.gov/nccdphp/promising_practices/pdfs/Heart.pdf).

University of Wisconsin-Extension, <http://www1.uwex.edu/ces/lmcourse>.

Kansas University Community Tool Box, <http://ctb.ku.edu>.

#### 5. Basis for Focus on the Seven Core Stroke Belt States

Using 1930–2001 age-adjusted stroke mortality rate data from the National Center for Health Statistics, South Carolina has ranked second or first in 8 of 8 decades (100 percent of the time), Georgia first or second in 6 of 8 decades (75 percent of the time), North Carolina seventh or higher in 8 of 8 decades (100 percent of the time), Alabama sixth or higher in 6 of 8 decades (75 percent of the time), Mississippi seventh or higher in 7 of 8 decades (97 percent of the time), Tennessee seventh or higher in 6 of 8 decades (75 percent of the time), and Arkansas ranks first as of the most recent 2001 analysis, demonstrating the most rapid increase of all states and the District of Columbia over the study period. Arkansas' stroke mortality rate ranking has moved dramatically from a

rank of 36th in 1940 and 1950 to 15th in 1960, to 7th or 8th in 1970–1980, to 3rd in 1990, and to 1st in 2001.

Dated: April 15, 2004.

**Nathan Stinson, Jr.,**

*Deputy Assistant Secretary for Minority Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N–0166]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Feeding Practices Study II

**AGENCY:** Food and Drug Administration, HHS

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary consumer survey about infant feeding and diet of pregnant women and new mothers.

**DATES:** Submit written or electronic comments on the collection of information by June 21, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Infant Feeding Practices Study II

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), FDA is authorized to conduct research and educational and public information programs relating to foods and devices. Under this authority, FDA is planning to conduct a consumer study about infant feeding and the diet of pregnant women and new mothers. The study will provide detailed information about foods fed to infants, including breast milk and infant formula; factors that may contribute to infant feeding choices and to breastfeeding success, including intrapartum hospital experiences, mother's employment status, mother's self confidence, postpartum depression, infant sleeping arrangements; and other issues of interest to FDA, including infant food allergy, and experiences with breast pumps. The study will measure dietary intake of pregnant women and new mothers. It will also be used as one component of an evaluation of the Department of Health and Human