Board of Governors of the Federal Reserve System, March 29, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–6524 Filed 4–1–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Genetics, Health, and Society; Office of the Secretary, HHS; Request for Public Comment

ACTION: Request for public comment on a draft report on coverage and reimbursement of genetic tests and services.

SUMMARY: The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comment on a draft report on coverage and reimbursement of genetic tests and services.

DATES: Written or electronic comments should be submitted by May 6, 2005.

ADDRESSES: Comments can be sent by mail to the following address: Secretary's Advisory Committee on Genetics, Health, and Society, attn: Suzanne Goodwin, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD, 20892. Comments also can be sent via e-mail to Suzanne Goodwin at *goodwins@od.nih.gov* or via facsimile to 301–496–9839.

FOR FURTHER INFORMATION CONTACT: Suzanne Goodwin, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, *goodwins@od.nih.gov*.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. For more information about the Committee, please visit its Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

In its first year, SACHGS identified coverage and reimbursement of genetic tests and services as a high priority because there are significant barriers to coverage and reimbursement as well as unmet data needs that are currently limiting appropriate access and clinical integration.

Its report, Coverage and Reimbursement of Genetic Tests and Services, describes the current state of, and problems associated with, coverage and reimbursement for genetic tests and services and offers recommendations on how current mechanisms for coverage and reimbursement for genetic tests and services might be improved. Once finalized, the report and recommendations will be transmitted to the Secretary of Health and Human Services.

SACGHS proposing to make the following recommendations in its report to the Secretary:

1. The Secretary should task an appropriate group or body to develop a set of principles to guide coverage decision making for genetic tests. The principles should identify criteria to help determine which types or categories of genetic tests should be covered, which should not be covered, and which fall into an uncertain gray zone. The group's guiding principles should address the issues of economic evaluation/cost-effectiveness, prevention, rare disease tests, and therapeutic versus informational benefit. The Committee also recommends that the existing evidence for specific tests be assessed in order to determine whether the evidence is adequate in type, quality, and quantity to establish analytical validity, clinical validity and clinical utility as well as to identify any gaps in evidence.

This body should include both relevant HHS agencies and private organizations and utilize resources of models in the public and private sector. The Evaluation of Genomic Applications in Practice and Prevention Work Group organized by the Centers for Disease Control and Prevention involves such a diverse range of stakeholders and is performing similar work and, thus, is an example of such a body to be tasked to develop these principles and address these issues.

The Committee also recommends a mechanism be established that would specifically promote and fund studies to address any identified gaps in the evidence base.

2. Genetic tests and services in pediatrics and those with a prevention component should be considered specifically with respect to the benefits they can offer the populations they serve. Although standardization of coverage decisions using best scientific evidence across public and private payers is ideal (see Recommendation 1), private payers should be supported with necessary information to make their own coverage determinations about these tests and services relative to the populations they serve.

3. Although a mixed national-local coverage decision-making process is a reasonable approach to making Medicare coverage decision for genetic tests and services, there are several aspects of the current national-local decision-making process that limit its utility. While not suggesting changes to the current system, SACGHS recommends that the Secretary encourage the Centers for Medicare & Medicaid Services (CMS) to move forward with the implementation of Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires the development of a plan to evaluate new local coverage decisions to determine which should be adopted nationally and to what extent greater consistency in Medicare coverage policy can be achieved.

4. Medicare beneficiaries who lack current signs, symptoms, or personal histories of illness stand to clinically benefit from predictive and predispositional genetic tests and services. As such, SACGHS recommends that preventive services, including predispositional genetic tests and services, meeting evidence standards should be covered under Medicare.

The Secretary should urge Congress to add a benefit category for preventive services that would enable CMS to determine through its national coverage decision-making process, which includes an assessment of existing evidence, whether an item or service is reasonable and necessary for the prevention or early detection of an illness or disability and, thus, ought to be covered. Such action would allow CMS to consider covering many more genetic tests and services that are used for preventive purposes.

More immediately, the Secretary should direct CMS to clarify, through appropriate guidance, that in certain circumstances and where scientific evidence warrants, ''personal history'' may include family history of a particular disease for purposes of establishing that a genetic test is ''reasonable and necessary'' and, therefore, covered under Medicare. CMS should specify the circumstances and criteria required to make such a determination.

5. The Secretary should broadly disseminate to all states information about the existing evidence base and other supporting information, such as guiding principles that serve as the basis for coverage decision-making, on genetic tests and services. This information could be utilized by the

states to inform their Medicaid coverage decisions.

HHS should continue to provide states with grants that encourage the coverage, adoption and provision of genetic services that have a sound evidence base.

6. In many cases, payment rates for genetic tests are lower than the actual cost of performing the test. Until the fee schedule can be reconsidered in a comprehensive way, the Secretary should direct CMS to address variations in payment rates for the genetic test Current Procedural Terminology (CPT) codes through its inherent reasonableness authority.

7. Genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services. As such, SACGHS recommends the following:

- Qualified health providers should be allowed to bill directly for genetic counseling services. The Secretary should expeditiously identify an appropriate mechanism for determining the credentials and criteria needed for a health provider to be deemed qualified to provide genetic counseling services and eligible to bill directly for them.
- The Secretary should direct government programs to reimburse prolonged service codes when determined to be reasonable and necessary.
- HHS, with input from the various providers of genetic counseling services, should assess the adequacy of existing CPT Evaluation & Management (E&M) codes and their associated relative values with respect to genetic counseling services. Any inadequacies identified should be addressed as deemed appropriate.
- CMS should deem all non-physician health providers who are currently permitted to bill directly any health plan—public or private—eligible for a National Provider Identifier.
- The Secretary should direct CMS to allow non-physician health professionals who are qualified to provide genetic counseling services and who currently bill incident to a physician to utilize the full range of CPT E&M codes available for genetic counseling services.

8. Since providers act as intermediaries between health plans and plan members and thus have an important role in ensuring genetic tests and services are provided appropriately, there is a need to support the ongoing training and continued education of health providers in genetics and genomics. SACGHS's recommendations to the Secretary in 2004 included the following: the Secretary should develop a plan for HHS agencies to work collaboratively with state, federal and private organizations to support the development, cataloguing and dissemination of case studies and practice models that demonstrate the current relevance of genetics and genomics; and the Secretary should strive to incorporate genetics and genomics into relevant initiatives of HHS, including the National Health Information Infrastructure.

9. Reliable and trustworthy information about family history, genetics and genetic technologies should be developed and made more widely available through the internet and other mechanisms that allow patients and consumers to evaluate health plan benefits and health providers so that they may make the most appropriate and most financially responsible decisions for themselves and their families.

The Secretary should leverage HHS resources to develop and make widely available reliable and trustworthy information about genetics and genetic technologies to guide and promote informed decision making by healthcare consumers and providers. Such information should be made available though federal government Web sites and other appropriate mechanisms.

The full report is available electronically at *http://www4.od.nih.gov/oba/sacghs/public_comments.htm*. A paper or electronic copy also can be requested by calling the NIH Office of Biotechnology Activities at 301–496–9838– or by e-mailing Suzanne Goodwin at *goodwins@od.nih.gov*.

SACGHS is requesting comments on these recommendations and the overall content of the draft report. Public comments received by May 6, 2005, will be considered by SACGHS in preparing the final report. The report and the public comments will be discussed at SACGHS's next meeting on June 15–16, 2005, in Bethesda, MD. Comments also will be available for public inspection at the NIH Office of Biotechnology Activities Monday through Friday between the hours of 8:30 a.m. and 5 p.m.

Dated: March 28, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–6614 Filed 4–1–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Preventing Sexual and Intimate Partner Violence Within Racial/Ethnic Minority Communities

Announcement Type: New.

Funding Opportunity Number: RFA 05043.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates: Letter of Intent Deadline: May 4, 2005.

Application Deadline: May 19, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under section 391(a) of the Public Health Service Act (PHS Act), 42 U.S.C. 280b(a), section 393 of the PHS Act, 42 U.S.C. 280b–1a.

Background

The National Violence Against Women Survey (NVAWS) reports that approximately 1.5 million women are raped and/or physically assaulted by an intimate partner each year. Violence against women is a significant public health and criminal justice concern which disproportionately affects marginalized groups such as racial and ethnic minorities. This study further reports the racial and ethnic differences in the lifetime rates of rape, for example American Indian/Alaska Native women were identified as having almost twice the rate of African American or White women. Specifically, American Indian/Alaska Native women (34 percent) were significantly more likely to report that they were raped than African American women (19 percent) or White women (18 percent). The survey also found that women who identified themselves as Hispanic (14.6 percent) were significantly less likely to report they had ever been raped than women who identified themselves as non-Hispanic (18.4 percent). Additionally, American Indian/Alaska Native women (30.7 percent) were most likely to report Intimate Partner Violence, and Asian/Pacific Islander women (12.8 percent) were least likely to report Intimate Partner Violence. Other racial differences illustrate that close to one-third of African American women experience intimate partner violence in their lifetimes compared with one-fourth of White women. Furthermore, when you consider the rates for the most severe form of intimate partner violence, which is homicide, African American women (3.55) are three times as likely than White women (1.11) to die