

Regional and Community Bank Group)  
101 Market Street, San Francisco,  
California 94105-1579:

1. *Palomar Enterprises, LLC*; to become a bank holding company by acquiring 18.3 percent of the voting shares of Farmers & Merchants Bank of Long Beach, both of Long Beach, California.

Board of Governors of the Federal Reserve System, November 1, 2007.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. E7-21753 Filed 11-5-07; 8:45 am]

**BILLING CODE 6210-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Secretary's Advisory Committee on Genetics, Health, and Society

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Request for public comment on a draft report on the oversight of genetic testing.

**SUMMARY:** The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comment on a draft report on the oversight of genetic testing.

**DATES:** Written or electronic comments should be submitted between November 5, 2007 and December 21, 2007.

**ADDRESSES:** Comments should be e-mailed to SACGHS in care of Cathy Fomous, PhD, at [cfomous@od.nih.gov](mailto:cfomous@od.nih.gov). Comments can also be mailed or faxed to Dr. Fomous's attention at the NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 700, Bethesda, MD, 20892 or fax number 301-496-9839.

**FOR FURTHER INFORMATION CONTACT:** Cathy Fomous, PhD, NIH Office of Biotechnology Activities, at [cfomous@od.nih.gov](mailto:cfomous@od.nih.gov) or 6705 Rockledge Drive, Suite 700, Bethesda, MD 20892, 301-496-9838.

**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 policy 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 the Web site: <http://www4.od.nih.gov/oba/sacghs.htm>.

In 2004, SACGHS recognized that oversight of genetic testing was a high-priority issue that required ongoing monitoring. In 2006, SACGHS began an in-depth fact-finding process on the oversight roles of Federal, State, and

private sector entities. In March 2007, the Office of the Secretary of HHS outlined a specific charge to SACGHS to focus the Committee's inquiry. The charge reads as follows:

Undertake the development of a comprehensive map of the steps needed for evidence development and oversight for genetic and genomic tests, with improvement of health quality as the primary goal. Consider and address the following questions:

- What evidence of harm exists regarding genetic tests? Is that harm attributable to analytic validity, clinical validity, or clinical utility of the tests? If evidence does not exist, what threats are not currently being addressed? What public health benefits are not accruing as quickly as they might?
- What distinguishes genetic tests from other laboratory tests for oversight purposes?
- What are the existing pathways that examine the analytic validity, clinical validity, and clinical utility of genetic tests? Consider the use of case studies.
- What organizations are currently involved with each of these aspects, and what are they doing to address these issues? Who should be responsible for each of these aspects?
- What resources (e.g., standards reagents/materials) are needed to develop proficiency testing kits or protocols for genetic tests? What is currently available in terms of proficiency testing kits or protocols for genetic tests? What information is provided by proficiency testing? Is the current level of proficiency testing for genetic tests adequate and are the results of such laboratory performance assessments sufficiently transparent?
- What are the potential pathways to communicate clear information to guide test and treatment selection by the provider?
- What new approaches or models should be considered for private and public-private sector engagement in demonstrating clinical validity and clinical utility for developing effectiveness measures of genetic tests in clinical practice?
- Would additional or revised Government oversight add value for patients, and if so, how and where?

SACGHS organized a task force to explore the questions outlined in the Secretary's charge and gather facts and perspectives on how best to address them. With the help of the task force, SACGHS drafted a report that addresses the issues and offers a number of recommendations for enhancing the oversight of genetic testing in the U.S. A copy of the draft report, *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS*, will be available from November 5, 2007 to December 21, 2007 at [http://www4.od.nih.gov/oba/sacghs/public\\_comments.htm](http://www4.od.nih.gov/oba/sacghs/public_comments.htm). A paper or electronic copy also can be obtained through the NIH Office of Biotechnology Activities at 301-496-9838 or by

e-mailing Dr. Fomous at [cfomous@od.nih.gov](mailto:cfomous@od.nih.gov).

SACGHS would welcome comments on any aspect of the report. In particular, SACGHS would appreciate input on whether the draft report: (1) Fully responds to questions posed by the HHS Secretary; (2) proposes appropriate remedies to close gaps in the current system; and (3) adequately anticipates future developments in the field of genetics/genomics that may bear on the oversight of genetic testing. In addition to submitting written comments, the public will have an opportunity at the SACGHS meeting on November 19-20, 2007 to provide testimony on this topic. The meeting is being held at the Ronald Reagan Building, Washington, DC (see <http://www4.od.nih.gov/oba/SACGHS/SACGHsMTGIndex.HTM> for a meeting agenda). All comments received by December 21, 2007 will be considered by SACGHS in preparing its final draft report. Public comments 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: October 29, 2007.

**Sarah Carr,**

*Executive Secretary, SACGHS.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

**Title:** OCSE-100, State Plan Preprint Page; OCSE-21-U4, State Plan Transmittal.

**OMB No.:** 0970-0017.

**Description:** Section 7310 of the Deficit Reduction Act of 2005, titled, *Mandatory Fee for Successful Child Support Collection for a Family That Has Never Received TANF*, amends Section 454(6) of the Social Security Act (the Act) such that a State child support plan must provide for the imposition of an annual fee of \$25 in each case in which an individual has never received assistance under a State program funded under title IV-A of the Act and for whom the State has collected at least \$500 of support. States will need to submit the new State plan preprint page, i.e., page 2.5-4, as well as a transmittal for the preprint page, in order to have an approved State plan.