

Coverage and Reimbursement of Genetic Tests and Services:

Review of Public Comments and Finalization of SACGHS Report

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Session Purpose and Goals

- To provide overview of report
- To review public comments on draft report
- To finalize report and recommendations

Report's Premise and Purpose

- **Problem Statement**

- Problems with coverage and reimbursement of genetic tests and services are limiting their accessibility and integration into the health care system

- **Purpose**

- To describe the current state of, and problems associated with, coverage and reimbursement of genetic tests and services
- To offer recommendations on how current mechanisms for coverage and reimbursement of genetic tests and services might be improved

- **Objective**

- To improve appropriate access to and utilization of health-related genetic tests and services by ensuring appropriate coverage and reimbursement throughout the health care system

Proposed Recommendations

1. Evidence-based coverage decisions
2. Influence of Medicare on private plans
3. National vs. local Medicare coverage policies
4. Medicare screening exclusion
5. Medicaid and SCHIP coverage
6. Medicare Clinical Laboratory Fee Schedule
7. Billing and reimbursement of genetic counseling services
8. Public awareness
9. Provider education and training in genetics

Report Timeline

March 2004	Presentations by various experts
June 2004 – March 2005	Discussion of four iterations at three meetings
April-May 2005	Request for public comments
May 26, 2005	Task Force conference call
June 15-16, 2005	Review public comments and finalize recommendations
Summer 2005	Final revisions to report
Fall 2005	Expected transmittal of report to Secretary

Public Comment Process

- Public comment period: April 4 – May 6, 2005
- Four outreach mechanisms:
 - SACGHS website
 - Federal Register notice
 - SACGHS distribution list
 - Targeted mailing to 34 individuals and organizations with particular expertise on topics discussed in report

Public Comment Response

- 86 public comments:
 - 61 individuals
 - 25 organizations
- Perspectives represented:
 - Health providers: physicians, genetic counselors, nurses, laboratorians, hospitals, clinics, private practices, public health agencies
 - Health plans: medical directors, actuaries
 - Academia: clinical professors, health economists
 - Patients/consumers
 - Students

Human Genetics Final Exam

The Secretary of Health and Human Services established the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) in 2002 as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic tests. Several meetings of SACGHS have been held since its establishment and a draft report was released in April 2005 entitled *Coverage and Reimbursement of Genetic Tests and Services*. This report includes nine specific recommendations (see below) and is available online at the [SACGHS web site](#). Public input on this 98-page report will be accepted until 6 May 2005.

For your final exam, you are expected to read this report and make substantiative comments relating to the potential recommendations (presented in blue boxes in the report). Specifically, you should make comments relative to each of the following recommendations:

1. "The Secretary should task an appropriate group or body to develop a set of principles to guide

Task Force Conference Call

May 26, 2005

- Reviewed public comments
- Developed modifications to the recommendations for SACGHS to consider

Overarching Themes Emerging from Public Comments

- Generally positive about draft recommendations in terms of the importance of the issues they address and SACGHS' approach to addressing them
 - Some concerns expressed about the characterization of the extent of the access barrier
 - Different approaches proposed for refining recommendations
 - Information provided to help clarify technical points made in body of report

Overarching Themes Emerging from Public Comments

- Anecdotes provided that illustrate link between inadequate coverage and reimbursement and access problems
- Comments provided that illustrate problems resulting from inadequate reimbursement and billing mechanisms for non-physician genetic counseling providers
 - Out-of-pocket payment by patients
 - Reluctance to refer patients
 - Problems finding and maintaining employment
 - To supplement salary, time used doing research instead of seeing patients

Overarching Themes Emerging from Public Comments

- Significant number (44%) encouraged SACGHS to specifically recognize ABGC and GNCC in recommendation regarding direct billing
- Report should consider impact of recommendations on health care resources and long-term financing capacity of health care system

**Specific Public Comments on
Each Recommendation and
How the Task Force
Addressed Them**