Public Comments: Coverage and Reimbursement of Genetic Tests and Services

June 2005

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

Individuals

Goodwin, Suzanne (NIH/OD)

From: David Aughton, MD [DAUGHTON@beaumont.edu]
Sent: Tuesday, May 03, 2005 4:26 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: comment on Draft Report on Coverage and Reimbursement ofGenetic Tests and Services

I am writing to offer a comment on the Draft Report. I must first admit that I have not read the Draft Report cover to cover, although I must say that it does appear to me from the reading that I *have* done to be a very impressive document; I think that those who have worked on it are to be commended.

My comment is minor but, I think, nevertheless important. On page 20, the Draft Report states in part, " . . . genetic tests and services are typically covered under the following circumstances, as appropriate: . . . The patient has risk factors or a particular family history that indicate a genetic cause." It has been my personal experience that tests and services that are ordered solely because of a positive family history are rarely if ever considered to be covered benefits.

As you well know, circumstances in which a person who is not currently sick encounters the health system are typically designated under ICD-9-CM by V codes (such as, for example, V16.3 ["family history of malignant breast neoplasma"], V17.2 ["family history of certain {other} neurological diseases"], V18.4 ["family history of mental retardation"], and V19.5 ["family history of congenital anomalies"]). Although nothing in ICD-9-CM suggests that such circumstances are less worthy of insurance coverage than are circumstances designated by non-V codes, many health insurers appear to consider any procedure performed for an indication designated by a V code to be not covered, apparently under the misguided assumption that people who are not currently sick have no business encountering the health system. Thus, for example, while having a child with an unbalanced chromosomal translocation is a perfectly legitimate reason for a parent to undergo chromosome analysis, it has been my personal experience that many (and perhaps most insurers) will not cover parental chromosome analysis for that indication, since the circumstance is most appropriately designated by a V code.

Although it is sometimes possible to circumvent these problems, I have nevertheless found this practice to be a *huge* impediment to the smooth obtaining of needed genetic services. I therefore do not think it is true that "genetic tests and services are typically covered . . . [for] a particular family history that indicate[s] a genetic cause".

A more generic comment concerning that same page: It is not clear to me whether the various members of the list of genetic tests and services that are typically covered (current signs and symptoms, inconclusive conventional diagnostic procedures, risk factors or family history, &c.) are intended to be joined by "AND" or instead by "OR"; that is, it is not clear to me whether genetic tests and services would typically be covered for any one member of the list considered in isolation (as I suspect is the intent of the list), or whether instead genetic tests and services would typically be covered only if each and every member of the list is satisfied.

If the former, however, it is not the case that genetic tests and services are covered, for example, simply because they are being performed by a CLIA-certified laboratory (wouldn't it be great if they were??). And if the latter, it is also not the case that, for example, a patient must have current signs and/or symptoms and must have risk factors or a positive family history; if a person is symptomatic, they don't necessarily need a positive family history (although the test does have to be performed by a CLIA-certified laboratory and cannot be experimental or investigational). The various members of the list do not individually seem to be either necessary or sufficient to secure coverage; I am therefore uncertain of the relationship that is being implied exists among them.

(Just for your consideration.)

Many thanks.

David J. Aughton, MD, FAAP, FACMG
Chief, Division of Genetics
Department of Pediatrics
William Beaumont Hospital
3535 West Thirteen Mile Road
Suite 707
Royal Oak, Michigan 48073 USA
telephone: 248 551-0487
telefacsimile: 248 551-5998

Memorial Health
University Physicians

Savannah Perinatology Associates

Harold A. Bivins, Jr., MD
Director, Maternal-Fetal Medicine

W. Lynn Leaphart, MD
Associate Director, Maternal-Fetal Medicine

Anthony B. Royek, MD
Associate Director, Maternal-Fetal Medicine

Tahnee N. Causey, MS
Genetic Counselor

Elizabeth E. Hull, MS
Genetic Counselor

April 26, 2005

Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Sir/Madam:

On behalf of our maternal-fetal medicine practice group and the patients we serve in the southeast Georgia area, we are writing to address our concerns regarding billing and reimbursement for genetic counseling services. As the only perinatology practice in our region, our physicians and genetic counselors provide an invaluable service to both individuals and their families. In addition, our roles as members of a teaching institution and county hospital provide us with the opportunity to work with, educate, and assist both fellow professionals and their patients.

While the draft report from the SACGHS has suggested significant improvements to the current status for billing and reimbursement of genetic services, we would like to further address comments made in recommendation #7. The process of certification of all North American genetic counselors through the American Board of Genetic Counseling (ABGC) is a rigorous process, requiring competencies on many levels of both medical genetics and medicine in general. Based upon the training, education, and certification process, ABGC-certified genetic counselors should be recognized as qualified non-physician health providers. This recognition, as bestowed upon other qualified non-physician professionals, such as physicians assistants and nurse practitioners, should enable genetic counselors to receive a national provider identifier, as well as enable them to bill both governmental and private health insurers independently.

The ability to bill independently is mutually beneficial to patients and health practitioners alike. Certified genetic counselors are specifically trained to understand and explain the complicated new technologies and resulting health implications often unique to the field of medical genetics. These concepts are often complex and require detailed consultation that can more effectively and economically be provided by certified genetic counselors, rather than their physician counterparts. Amending existing E&M codes to reflect the complexity and length of time of genetic consultation should therefore be considered.

While one of the newer health professions, genetic counseling has rapidly become a crucial part of current medical practice. The lack of recognition of certified genetic counselors as qualified providers, as well as the lack of appropriate reimbursement, could prove detrimental to many hospitals, including county hospitals such as ours. Encouraging medical institutions to provide genetic counseling services, and recognizing these services as crucial and medically reimbursable, is a key role for the SACGHS, as well as the Department of Health and Human Services as a whole.

We appreciate your time and consideration and express sincere hope that these opinions will be duly noted and emphasized in the final report of your committee.

Sincerely,

Harold A. Bivins, Jr., M.D.
Director, Maternal-Fetal Medicine

Tahnee N. Causey, M.S., C.G.C.
Genetic Counselor

Elizabeth H. Malphrus, M.S., C.G.C.
Genetic Counselor

JOHNS HOPKINS
UNIVERSITY

Department of Gynecology and Obstetrics
Division of Maternal-Fetal Medicine
The Johns Hopkins Hospital
600 N. Wolfe Street / Phipps 228
Baltimore MD 21287-1228
410-955-8496 / Fax 410-614-8305
Nights and Weekends
410-955-4331 or 410-955-5850

May 2, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

Re: Coverage and Reimbursement of Genetics Tests and Services

Dear Ms. Goodwin:

I am writing in support of the draft report of the Secretary's Advisory Committee on Genetics, Health, and Society with focus on the importance of billing for genetic counselors' services. As you know, genetic counselors are professionals who have completed a master's program in medical genetics and counseling. The certification of genetic counselors through the American Board of Genetic Counseling provides the means of identifying qualified health providers who should be eligible to bill directly for their relevant services. Genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services. I further support the draft report's focus on a CPT evaluation and management system so that qualified genetic counselors are eligible for a National Provider Identifier and may utilize the full range of CPT evaluation and management codes available for genetic counseling services. I am in support of the Department of Health and Human Services (with input from providers of genetic counseling services) to conduct an evaluation of codes and their associated relative values and addressing any code inadequacies with respect to genetic counseling services.

As Director of the Prenatal Diagnosis and Treatment Center at The Johns Hopkins Hospital, I can personally attest to the importance of the genetic counseling services at our own Institution. Our counselors work as members of our health care team, providing information and support to families who have members with birth defects or genetic disorders and to families who may be at risk for a variety of inherited conditions. They identify families at risk, investigate the problem present in the family, interpret information about the disorder, analyze inheritance patterns and risks of recurrence, and review available options with the family. They also provide supportive counseling to families, serve as patient advocates and refer individuals and families to community or state support services. They serve as educators and resource people for other health care professionals and for the general public. Our counselors also work in

administrative capacities and engage in research activities related to the field of medical genetics and genetic counseling. Genetic counselors require a knowledge base and skills that are distinct from other health care professionals. The family's ability to make informed decisions about genetic testing, medical management, and lifestyle depends on the qualifications and competence of the health professional providing genetic counseling services. Informed consent and test interpretation are critical to informed patient decision-making.

I also believe that reimbursement for genetic counseling services will provide decreased costs and increased access for patients and their families, as well as the entire health care system. Prenatal genetic counseling services provide for a higher magnitude of risk identification, more awareness at delivery, and subsequently, lower costs. I am particularly drawn to one potential harm of non-reimbursement of genetic counseling services. That being, that most centers which provide genetic counseling services no longer are funded by grant support. It is thus my fear that non-reimbursement for genetic counseling services could lead to possible career changes due to the lack of salary support; with the growing need for genetic counseling services, a decrease in qualified genetic counselors would make it more difficult to meet the needs, and there would be increasingly unequal access to such services.

In summary, I support that certified genetic counselors are highly qualified health providers, that their value and effectiveness have been well proven and established, and that they are cost-effective in the health care system. I further support a CPT evaluation and management system so that qualified genetic counselors are eligible for a National Provider Identifier and may utilize the full range of CPT evaluation and management codes available for genetic counseling services, and most of all, I support that they are eligible and should be able to bill directly for their relevant services. I wish to extend my sincere gratitude to the Secretary's Advisory Committee on Genetics, Health, and Society for their extensive efforts and focus on these crucial issues. Please do not hesitate to call upon me if I may be of any assistance.

Sincerely,

Karin Blakemore

Karin J. Blakemore, M.D.
Associate Professor, Gynecology and Obstetrics
Director, Maternal-Fetal Medicine
Director, Prenatal Diagnosis & Treatment Center

KJB/dw

Goodwin, Suzanne (NIH/OD)

From: Shelly Bosworth [shellyqb@comcast.net]
Sent: Friday, April 29, 2005 5:49 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: ABGC billing comments

Michelle Queneau Bosworth
5031 Saxon Way
Eugene, OR 97405
541/554-5068 (cell)
shellyqb@comcast.net

April 29, 2005

Re: ABGC comment on draft report "The Coverage and Reimbursement of Genetic Tests and Services"

I am a part-time prenatal genetic counselor in Eugene, OR, board certified in 1999. Please see information copied from a Public Health Genetics Report (below) for information about the health demographic in Oregon. Basically, Oregon is mostly rural. Outside Portland, perinatologists practice in Eugene (population 140,000, 2 hours South of Portland) and Medford (population 80,000. 2 ½ hours South of Eugene). Perinatology is relatively new to Medford; an OB did a fellowship and returned to Medford in 1998. There are no board certified genetic counselors or genetics nurses in Medford.

In 2004 the hospital in Medford, Rogue Valley Medical Center, offered me a job. They wanted to equip my home office for telemedicine so that I could provide support to the patients of their perinatologist. **It fell through because they could not bill for my time.** Facility codes do not work because I am off-site. Incident-to codes do not work because I am at a different site than the perinatologist. Because they do expect adequate reimbursement billing in my name, the hospital postponed hiring me.

The perinatologist suffers as he is overworked and would prefer not to do psychosocial counseling. His patients suffer because he does not have the psychosocial training, nor desire, to adequately support them as they learn of fetal abnormalities. The most recent patient he referred to us in Eugene, for CVS, was considering termination based on the results of a screening test (ultrasound showing increased nuchal translucency). The residents in Oregon would have easier access to quality genetic health care if board certified genetic counselors could bill as the experts that we are.

Other developments in Oregon:
Medical geneticists from Oregon Health and Science University, in Portland, no longer come to Eugene. To be seen in a medical genetics clinic, all Oregon residents must commute to Portland. If board certified genetic counselors could bill for our time, clinical geneticist could more easily have a profitable practice outside the University setting.

Barb Petterson, an exceptional board certified genetic counselor in rural Bend, cannot convince the OBs that her services are valuable. Just as I cannot be a satellite provider for the perinatologist in Medford, she cannot be a satellite provider for our office in Eugene.

Thank you for your time. I hope this was helpful.

Best Regards and good luck,
Shelly

Excerpt:
http://www.dhs.state.or.us/publichealth/genetics/docs/orneeds02.pdf
Genetics and Public Health in Oregon:
A Summary of Assessment Methods & Findings
November 2002
Supported by a grant from the Maternal and Child Health Bureau
Grant # 4 H46 MC 00172-02-1

Though only the twenty-eighth largest by population density, Oregon is the ninth largest state in the nation by land mass (96,002 square miles).1 The most populous region of the state is the Interstate-5 (I-5) corridor, a north-south line stretching between the Washington and California borders, approximately sixty miles inland from the Pacific Ocean. Mountain ranges separate the I-5 corridor from the coastal region to the west and high desert region to the east, both largely rural and rugged areas. There is one large urban center, Portland, at the northern end of the I-5 corridor and several moderate sized communities along I-5 (Salem, Eugene, and Medford), one in central Oregon (Bend), and one in eastern Oregon (Pendleton). The rest of the state, the southeast in particular, is rural and sparsely populated. Large areas with small population densities and the presence of physical obstacles such as mountain ranges create challenges for health care service delivery. 1

While Oregon does not have an overall shortage of health care professionals, certain areas of the state have a low ratio of practitioners to total population. This unequal distribution of providers is a key concern for health care access. Based on a 1999 rural health report, the practitioner to population ratio was <1:400 in Oregon's only urban county (Multnomah), while in some rural areas the ratio was > 1:2500.12 According to the 1999 report, there were approximately 7331 practicing physicians, 695 nurse practitioners, and 182 physician assistants in Oregon. Of these, 79% of physicians, 72% of nurse practitioners, and 77% of physician assistants were in Oregon's urban and mixed urban/rural counties where 69% of the population lives.13 As will be discussed in further detail in later sections of this report, clinical genetics professionals (physicians and genetic counselors) are located mainly in the Portland metro area with a very limited number in other areas of the state. Other specialty providers are also in low supply in non-urban areas.

1 Encarta.com
10 From the Urban Institute, as reported by Covering Kids, www.coveringkids.org (2002 August).
11 Oregon DHS Perinatal Program estimates based on Citizen Alien Waived Emergent Medical data.
12 Oregon Health Council, *Access to Health Care in Oregon: Problems and Strategies*, Preliminary Draft (2002).
13 Oregon Rural Health Plan, www.ohsu.edu/oregonruralhealth/ (1999).

Shelly Queneau Bosworth, MS, CGC
5031 Saxon Way Eugene, OR 97405
541/342-2189 cell 541/554-5068
shellyqb@comcast.net

Goodwin, Suzanne (NIH/OD)

From: Brunskill, Andrew MD [ABru107@HCA.WA.GOV]
Sent: Wednesday, May 04, 2005 7:39 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comment on Coverage and Reimbursement of Genetic Tests and Servic es.

Dear Ms Goodwin,
I just wanted to comment on the report on Coverage and Reimbursement of Genetic Tests and Services. There are several cases that have presented themselves to me as a state health plan medical director which raise policy issues that I think might be helpful to be aware of.
1. Inadequate expertise by the provider ordering and interpreting the genetic test. We have had a few examples that we are aware of where patients received grossly incorrect risk counseling from providers (including specialists) who nevertheless had insufficient expertise in the particular area of concern. We now believe that using a groups of providers with formal qualifications (boards in medical genetics) and ideally specialization in the condition of interest is highly acceptable to the patients and reassures us that the patients are making decisions based on the best information. We are not convinced that clinical practitioners without this training are able to provide a satisfactory service. In this case the financial benefit to the plan of having the correct information transferred is very substantial. Issues like incorrect risk assessments for subsequent births and for the value of prophylactic mastectomy may involve substantial liability for a health plan.
2. Inefficient test ordering. Some of the test providers are now bundling tests which include tests for variants which are diminishingly rare. This has the effect that the provider and payer have to purchase a group of tests and use them in a simultaneous manner when a sequential approach emphasizing sequential exclusion of more common variants initially would be much more cost efficient for the payer.
3. We have found that requiring prior genetic counseling by formally qualified practitioners when the plan authorizes genetic testing (most of our experience is for breast cancer) is generally well accepted by the enrollees. Even in the rural areas our enrollees seem to accept the value of making a journey to see a well credentialled provider.
I am writing on my own behalf and not expressing the policy of the state.
Sincerely,

Andrew J Brunskill. Medical Director Uniform Medical Plan, State of Washington.

Goodwin, Suzanne (NIH/OD)

From: sbryant@cpdx.com
Sent: Friday, April 29, 2005 11:07 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Support for genetic counseling reimbursement

I am writing to you as a board certified genetic counselor working in the fields of prenatal and male infertility counseling. I have been a practicing counselor for 4 years and I primarily work for a maternal fetal medicine specialist who has a small but busy private practice. Recently, due to new billing requirements by SMFM, we were forced to minimize my billable time for consults to only the amount of time the MFM is present in the room. This has been a major challenge in our practice due to the busy nature of our office. We have only one MFM and he has to juggle daily to be in consult with patients receiving genetic counseling for various complicated issues, reviewing ultrasounds during patient appointments, consult patients for ongoing management of high-risk pregnancy in regular office visits and during rounds at the hospital, and regularly deliver high-risk patients.

At a time when there are fewer and fewer OBs, there are even fewer MFMs. The patients we care for regularly, or even see in consult on a one-time basis, usually involve a great deal of time and attention to detail. These patients also require more information, ongoing support, and reassurance. As a genetic counselor, I have the qualifications and experience to effectively translate complicated genetic and medical information to patients. Although our MFM is involved in all of our patient consults, it is simply not possible for him spend the time needed for them to understand their situation. We probably perform over 80% of the consultation and then he comes in to reiterate our statements. He is able to confidently rely on the ability of me and the other genetic counselor in our practice to manage the majority of the care required, and then step in as needed. In many cases, we have more expertise about some of the rare genetic conditions than he does, and his focus is more on their pregnancy management and reading ultrasounds or performing prenatal testing procedures. We work together as an effective team to provide the best possible obstetrics care.

As a prenatal genetic counselor, I am able to explain complicated screening and testing options and results to physicians, (who regularly call with questions) as well as our patients. We frequently have families with history of serious genetic conditions, both known and unknown, and I have been trained to evaluate risk for these anxious couples by taking a detailed medical history and analyzing family pedigrees. I also care for patients facing the difficult option of pregnancy termination or continuing of an abnormal pregnancy. I spend a great deal of time with these couples explaining the fetal condition and making sure they are supported in their decision making and pregnancy and post-natal management.

I truly enjoy my work as a genetic counselor, despite the challenges of this profession. I am frequently thanked by couples with normal and abnormal pregnancy outcomes, who tell me how grateful they are for the time spent in their care to reach a better understanding of their circumstances. Although many of families do not have a happy ending, I do my best to ease the pain of loss they may feel.

I wish we were in an era when physicians had sufficient time to spend all the time needed for ideal patient care. But the reality of medicine today is that physicians must rely on other members of their health care team to assist in, and at times, perform the majority of this medical consultation and care. Genetic counselors have the unique ability to clearly explain very complicated information to patients, which helps families make more informed decisions about complex issues. Although the consult time involved is initially longer than the average medical consultation, the overall care, efficiency and patient satisfaction is greatly improved in our practice when a genetic counselor is utilized.

In my opinion, minimal reimbursement for genetic counseling services leads to compromed patient care. This is because many MFMs cannot afford to hire a counselor and without a counselor available to thoroughly manage patients, the MFM is seriously challenged to provide sufficient care. There are MFMs in our area who practice without a counselor, and

frequently we have to see their patients for secondary consultation. Frequently these patients have come in thoroughly confused and indicating they did not hardly spend any time with the MFM, which led to the request for a new consultation. After taking time with these patients, they usually report a much clearer understanding and are able make decisions in their pregnancy.

I did not go into this field with the thought that it would make me wealthy. But I also did not expect to work in an unpaid or minimally funded position. Time and time again, I hear physicians from many fields say how much they would love to hire a counselor because of how helpful they are in a practice. Unfortunately, without better reimbursement, they cannot afford to hire one. In this era of growth of information about human disease in relation to genetics, genetic counselors are invaluable contributors to effective patient care. Without reimbursement, medical institutions have greater liability. But more importantly, patients will not receive optimal care when the understanding of these complicated conditions is minimized by the current health care model.

Please do your part to encourage reimbursement of genetic counseling services.

Sincerely,

Stephanie L. Bryant, MS, CGC
Center for Prenatal Diagnosis
Indianapolis, IN

Goodwin, Suzanne (NIH/OD)

From: Adam Buchanan [bucha012@mc.duke.edu]
Sent: Friday, May 06, 2005 11:37 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comment on SACGHS draft recommendations

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society

Ms. Goodwin,

I am writing to commend the Secretary's Advisory Committee on Genetics, Health and Society for its substantive recommendations on coverage and reimbursement of genetic testing and genetic services. As a cancer genetic counselor in Duke Comprehensive Cancer Center's Hereditary Cancer Clinic, I recognize the importance of thorough, comprehensive policy regarding this issue.

My one comment on the Committee's recommendations pertains to recommendation #7 (p. 52). I fully agree that qualified non-physician genetic counselors should be able to bill directly for genetic counseling. Allowing them to do so would greatly improve access to genetic counseling in medically underserved areas. However, the recommendation is ambiguous regarding what qualifications genetic counselors should have. I strongly suggest the recommendation be revised to state clearly that only ABGC-certified genetic counselors be recognized as qualified genetic counselors with the ability to bill independently for genetic counseling.

Only ABGC-certified genetic counselors have the unique training necessary to adequately counsel patients about the complex genetic, medical and psychosocial issues involved in genetic testing. Failure to specify qualifications necessary to be covered as a genetic counselor could be a detriment to patient care.

The Committee has produced an impressive document; by incorporating the above suggestion I believe it can be even stronger.

Thank you for your consideration.

Sincerely,

Adam H Buchanan, MS, MPH
Genetic Counselor, Clinical Research Coordinator
Duke Comprehensive Cancer Center
2424 Erwin Rd., Suite 602
Durham, NC 27705
phone (919) 668-0766
pager (919) 970-6485
fax (919) 681-4766
adam.buchanan@duke.edu

Goodwin, Suzanne (NIH/OD)

From: Caro, Susan [susan.caro@Vanderbilt.Edu]
Sent: Tuesday, May 03, 2005 12:02 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: SACGHS proposal reimbursment

Ms. Goodwin,
I appreciate the opportunity to comment on the SACHS proposal on reimbursement for genetic services. I am a nurse practitioner, Director of the Family Cancer Risk Service of the Vanderbilt-Ingram Cancer Center in Nashville. I applaud the committee for defining those appropriate to provide genetic services to include nurse practitioners and physicians, and not restricting your definition to medical geneticists and genetic counselors. As an advanced practice nurse, one of the first group to be credentialed by the GNCC as an advanced practice nurse in genetics, and a provider of cancer risk assessment and counseling to patients for over 10 years, I hope that any such formal statements do not give the impression that such care can only be provided medical geneticists or genetic counselors, or have the potential to restrict the services provided by individuals such as myself. I work and have worked in collaboration with a genetic counselor, but I know that many nurses provide this service throughout the country.

In reviewing the draft, in several places it does appear that genetic services could/should only be provided by genetic counselors or medical geneticists (example on page 13, another on page 15). In reality, access to genetic counselors or medical geneticists may not be possible. Many of the leaders in the field of hereditary cancer risk assessment are nurses and physicians whose roots are in other fields, such as oncology, family care, women's health, or surgery. My supervising physicians have included surgical oncologists, pathologists, and at one point a geneticist.

I wanted to encourage that the wording throughout the document be inclusive of all health care providers who may provide these services, and commend your group on the inclusion of such providers in the statement on provision of genetic services.
Thank you for your consideration and for the work that you do.

Susan W. Caro, RNC, MSN, APNG
Director, Family Cancer Risk Service
Suite 2900 Village at Vanderbilt
1500 21st Avenue South
Nashville, TN 37212
615.343.0738
877.688.7555
Fax 615.343.1819

Goodwin, Suzanne (NIH/OD)

From: Nancy Rehker [nrehker@metrohealth.org]
Sent: Monday, May 02, 2005 12:17 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Genetic Counselors

this message is from Dr. Patrick Catalano, Chairman and Professor, Dept. Ob/Gyn at MetroHealth Medical Center/Case Western Resere University

I am writing to inform you of my strong support of the ASGC's attempt to have the training and qualifications of genetic counselors. Our genetic counselor provides an invaluable service to our patients in education and support. As you know, dealing with genetic abnormalities is a very stressful and difficult time in a parent's life and our genetic counselor is available to explain to them the various causes, help them with their decision-making process by supplying them with the knowledge available, and support them in their decisions. Their support to our patients is invaluable. Sincerely, Patrick M. Catalano, M.D.

Goodwin, Suzanne (NIH/OD)

From: Trevor_Coon@whps.org
Sent: Thursday, May 05, 2005 3:51 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: some comments on recomendations in Coverage and Reimbursement of Genetic Tests and Services

The following are comments that I have arranged relative to various potential recommendations that were submitted in the draft report released in April 2005 entitled Coverage and Reimbursement of Genetic Tests and Services. I am hopeful this and other public input will guide the Secretary of Health and Human Services to make the right choices concerning genetic testing and services.

Comments regarding recommendation of Page 26:

It seems that "groups" or "bodies" are necessary in a democratic process. Some of my concerns about using specific factions are that these groups, like all interested parties, may have something to gain by pushing their assessment criteria. For instance, Blue Cross may have great technology assessments and review criteria that have been used industry-wide to make coverage decisions about which genetic tests will or will not be covered, but Blue Cross may not have the best interest of the beneficiaries in mind, after all, they are a business that needs to turn a profit. The point would be that if you are going to use a specific factions technology in making decisions about coverage or laws regarding coverage decisions, the company should really not stand to lose or gain anything from the outcome of the decision. I think the most important aspect of this recommendation is the fact that it is important to include (or represent) all interested parties in the "group" so that we get diverse recommendations and thereby create fair and unbiased decisions about what tests and procedures will be covered.

Comments regarding recommendation of Page 27:

I agree with the recommendation that it is very important to have sufficient information or evidence that a test has moved beyond the research phase is important. The more valid information we can collect on tests in question would promote a better decision in the long run. I think that care must be taken when considering test that may not provide
therapeutic options or demonstrate improved health outcomes. Care must also be taken when doing cost analysis of some of the prevention-based tests. Although they may seem expensive at the outset, they may well prove quite cost effective in their ability to detect diseases early and thus offset greater costs down the line. Both medical necessity and cost have to be weighed in the decisions on coverage, but in the case where decisions close, I believe the beneficiary's health issues should outweigh the issue of cost.

Comments regarding recommendation of Page 30:

I believe it is important to have both local and national coverage decisions. It seems the two work hand in hand to hopefully create greater consistency and sort of a check and balance. By limiting local coverage in favor of more national coverage, or vice versa, then we may see a loss of coverage altogether. Some would argue that there are inequities at the local level (conflicting LCD's), but without LCD's willing to provide coverage for medical test they deem important, it would probably be hard to make NCD's that would eventually apply to all beneficiaries in the future. It is important to achieve greater consistency, but not at the expense of coverage needed the most by patients.

Comments regarding recommendation of Page 32:

This recommendation seems like it would allow for coverage in cases where no sign of illness or personal history would warrant such coverage. I think it is important to note that even while using evidence-based medicine as a informative tool, we need to realize that results of experimental data provides more than one conclusion and therefore care must be taken when making coverage decisions in these

cases. In general, I believe moving towards coverage in these areas is a step in the right direction as long as the information gathered through experimentation supports the validity of the tests. The portion of the recommendation that urges congress to add a benefit category for preventive services may present problems. Not only would it allow the CMS to determine NCD's for specific genetic tests but would also allow a non-coverage decision to be made based on cost versus validity of test. If a non-coverage decision were made then this would preclude any contractors from making payment.

Comments regarding recommendation of Page 34:

It always seems in the best interest for all parties involved (in this case, the states, beneficiaries, local contractors, and CMS), that all information on evidence based medicine be made available to each faction and the general public so informed decisions can be made and opinions be voiced by all. Let everyone involved in the decision making process and the beneficiaries (general public) have access to this information so that everyone can formulate an educated opinion about coverage options. With available and valid information regarding these tests, beneficiaries will have the opportunity to put pressure on business and government to do the right thing.

Comments regarding recommendation of Page 45:

I think this recommendation makes sense as long as any abnormalities (excessive or deficient amounts) are scrutinized carefully. It seems that in most cases to date, payments are far less than real costs that are incurred by laboratories doing the genetic test in question. Since private laboratories probably run the majority of these tests, the CMS should direct fair reimbursement to these factions. This being said, the next question is whether or not inherent reasonableness will really work. By this, I mean, that the process of inherent reasonableness may take such a significant amount of time and resources, that it produces a lower rate of reimbursement anyways. If inherent reasonableness can be proven effective, then it seems like a logical avenue to take.

Comments regarding recommendation of Page 52:

My daughter was born with Down Syndrome seven years ago. Although I was somewhat familiar with the mechanism behind this disorder, my wife and I still sought genetic counseling. I believe that this is critically important to faced with questions and concerns regarding illnesses related to genetic defects or mutations. It provides those who are stricken with these illnesses the proper knowledge and supportive information necessary to make the right decisions about their future health care. It allows those that may not have the knowledge base about genetic testing and treatment to access health care providers that can guide them in an unfamiliar subject. I am convinced that as the number of genetic links to diseases increases so will the need for more education and genetic counseling. I see no reason why qualified individuals should not be able to utilize codes available for reimbursement as long as they fall within the guidelines set by the ABGC and GNCC.

Comments regarding recommendation of Page 54:

I think the key point in this recommendation lies primarily in fact that those who are making the decisions about coverage, generally business men and women and not physicians and geneticists, need to have an understanding of genetics and these specific tests in order to make informed choices about what will or will not be covered. I think we need to be sure that the decisions are based on scientific evidence and not just on profitability. Again, the dissemination of relevant and thorough case studies and fair practice models are important in making sure no bias occurs in the decisions on coverage.

Comments regarding recommendation of Page 55:

I think it is important to note that not all consumers feel comfortable with the subject of genetics and therefore it is imperative that the public be educated about genetic tests that may become available. This lack of knowledge on the part of the general public is specifically why there is such a need for the group who is formed to make the decisions about coverage without bias. Their foremost goal should be protecting the best interest of the beneficiaries who will either benefit of by hurt by decisions that are made.

Upon reflection of the above nine comments about the recommendations in the advisory committees report, I have come to the conclusion that a lot of factions have agendas (political, philosophical, economic, etc…) and a lot riding on the decisions that are made regarding these recommendations. I would ask that the secretary do everything possible to make sure that the decisions that are made about the use and coverage of genetic tests and genetic counseling are made in the best interest of the most important faction, the beneficiaries that rely on the use of these tests, the American citizens and taxpayers.

Sincerely,

Trevor M. Coon

Goodwin, Suzanne (NIH/OD)

From: Virginia Corson [vcorson@jhmi.edu]
Sent: Tuesday, May 03, 2005 2:16 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: comment on SACGHS report

To Whom It May Concern:

As a prenatal genetic counselor, I am pleased to read the Secretary's Advisory Committee on Genetics, Health, and Society draft document on "The Coverage and Reimbursement of Genetic Tests and Services". Your report supports the services provided by genetic counselors and the importance of establishing a billing mechanism for these services.

I would like to emphasize two issues addressed in the report. The American Board of Genetic Counseling (ABGC) certification process provides an appropriate mechanism for establishing the qualifications of genetic counselors and should be used as a standard for payer reimbursement. Currently, there is a billing/reimbursement crisis for genetic counseling services as institutions and counselors sturggle to find ways to bill insurance companies under current guidelines and restrictions. If third party payers cannot be billed for these services, patient access will be greatly curtailed and families may increasingly make decisions about complicated genetic testing without appropriate information.

I encourage the Committee to strengthen your recommendations by recognizing the ABGC certification credential as an important qualification for individuals providing these services. In addition, the importance and urgency of establishing a billing mechanism for genetic counseling should be emphasized.

Thank you.

Sincerely,
Virginia L. Corson, M.S., C.G.C.
Genetic Counselor
Johns Hopkins Hospital
Baltimore, MD 21287

Goodwin, Suzanne (NIH/OD)

From: Jane Corteville MD [jcorteville@metrohealth.org]
Sent: Sunday, May 01, 2005 8:42 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: ASGC

Genetic counselors are far better trained than most nurse practitioner. Our counselors are essential to patient care. The fact that they cannot bill is a travesty. the services they provide could not be provided by any physician in our group given our time constraints. Often it is the genetic counselor who raises issues of genetic testing with the MFM doctors (I am geneticist), since I cannot cover every clinic. The quality of patient care is so much better because of her presence. Thank you for your consideration. Jane E. Corteville, M.D. Director of Prenatal Genetic Services MetroHealth Medical Center

My comments on the potential recommendations are:

#1. I agree that a group should be formed to identify which genetic tests will be covered, and that the cost-effectiveness, benefit, and reliability of the tests should form the basis of the group's decisions. It is also important for the group to identify any gaps in the evidence base. Over time the group should reassess their decisions based on technological advances, which may improve reliability of the tests, reduce their cost, and alter the benefit.

#2. Private payers should be provided with information to make coverage determinations about genetic tests. Ideally, coverage for genetic tests in pediatrics and tests with a prevention component should be standardized. I agree with the potential recommendation that private payers make their own coverage determinations about these tests, because I would like the tests to be available to as many people as possible. If private payers are restricted too much, they may discontinue service.

#3. I agree with this potential recommendation to implement Section 731. There should be a plan in place to evaluate new local coverage decisions. This should ensure relevancy in determining which tests should be adopted nationally and to what extent greater consistency in Medicare coverage policy can be achieved.

#4. Coverage of predictive and predispositional genetic tests by Medicare would facilitate more timely approval from the private payers. Early detection of particular diseases may reduce treatment costs, provide greater treatment options, and improve treatment effectiveness. Therefore I agree with this potential recommendation.

#5. It is important to provide the evidence base to all of the states to aid in coverage decision making. I agree with this potential recommendation. Medicaid recipients should have access to genetic tests appropriate to their medical condition. The cost and effectiveness of the test should also be considered. This would help to maintain the effectiveness of the Medicaid system and provide consistency between Medicaid and Medicare.

#6. I agree with this potential recommendation. An attempt to standardize payment rates should be made. Also, the codes should be modified to include the purpose for the genetic testing. Patients should receive information concerning their test, and its ramifications. They should be asked if they still want to take the test. An attempt should be made to fit the code to the disease for genetic testing, and for genetic counseling, if possible. This would require medical personnel to be retrained for the modified codes.

#7. Genetic counseling is critically important for patients undergoing genetic testing. I agree with the potential recommendation. It would ensure that service be provided. The actual costs of the tests need to be determined. There is a need to have a reasonable law in place to allow flexibility in fee setting. The LabCorp process for securing adequate payment for genetic testing appears reasonable. Reasonable royalty fees should be paid based upon expert input. Genetic counselors should be licensed in order to ensure that they are qualified service providers and also to allow for their proper reimbursement.

#8. It is important for new tests to be utilized in order to obtain adequate data justifying the tests and to ensure coverage. As new technologies are developed, it becomes ever more necessary for interdisciplinary collaboration to take place. Thus, I agree with the potential recommendation.

#9. I agree that it is important for the general public to have reliable and trustworthy information concerning genetic testing and its implications. This is especially important because consumer decisions impact the availability of genetic tests from providers. 27

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
GENETIC SERVICES SECTION
20435 72ND Ave. South, Suite #200, MS K17-8
Kent, Washington 98032

May 5, 2005

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Dear Ms. Goodwin;

I am writing at this time to offer some input regarding the *Coverage and Reimbursement of Genetic Tests and Services DRAFT Report.* The Committee is to be applauded for its hard work at understanding the complex issues surrounding financing of genetic services and developing recommendations to address them. I have a few editorial comments that I wish to make, followed by a few global issues concerning the recommendations in general. To assist you in following these comments, I have identified relevant page numbers.

First, I would strongly encourage that the statement, "Since individuals' genetic information does not change over time, a specific genetic test only has to be performed once in their lifetimes," in the first paragraph on page 13 be omitted. While this statement may be true for germline mutations associated with disease, there are multiple instances in oncology, for example, where somatic cell mutations may be sought, necessitating in repeat testing. I believe simply removing this statement resolves the error. Also on page 13, 3rd paragraph, the suggestion that additional allied health care professionals may be necessary to offer social support services negates the fact that other health care professionals already mentioned do this as well (e.g., genetic counselors). I would suggest that the word "additional" be substituted for the word "necessary."

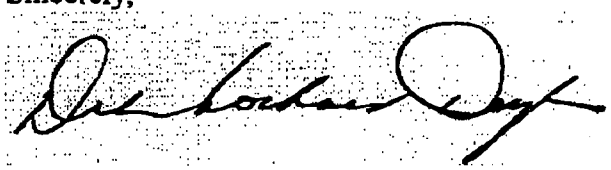
On page 20, 2nd paragraph, as it is currently written, one may assume that preimplantation genetic diagnosis is only available for the specified conditions listed, which is not true. I would revise this statement to read: "Of the coverage policies that are available, most cover genetic testing for chromosomal abnormalities, prenatal and neonatal diagnosis, and in some cases preimplantation genetic diagnosis for certain conditions (e.g., prior child with abnormality, advanced maternal age, etc.)." Similarly, in the last paragraph on this page, as written, one may understand that population screening without a famly history is not covered except for prenatal carrier screening

of cystic fibrosis. Again, this is not true as prenatal carrier screening for Tay Sachs disease, sickle cell disease and other hemoglobinopathies are frequently covered based on ethnic ancestry. My suggestion to correct this statement would be to simply place a period following prenatal and add "or preconceptional" carrier screening.

In closing let me share with you some general thoughts on the recommendations. First, the potential recommendations on page 52 are excellent although I would prefer to see it more clearly indicate the credentials of the "qualified health care providers." This is covered in the manual, but I believe it would be prudent to articulate these qualifications (i.e., ABMG/ABGC and or GNCC) within the text of the recommendation. I also question the recommendation regarding non-physician health providers who currently bill to be eligible for and National Provider Indicator (NPI) as it is my understanding that this is currently the policy. Finally, I question why the recommendation did not go so far as to recommend that HHS ask Congress to include genetic counselors and nurse geneticists as allied health care providers under Medicare Part B regulations? I recognize that such a recommendation may be considered lofty, yet the Committee has been asked for recommendations to resolve the issues and this certainly would be one additional avenue for addressing reimbursement that may be particularly important for people with disabilities or low income families on Medicaid or Medicare.

Again, I wish to offer my appreciation and gratitude for the fine work the Committee has done and hope that my comments may be useful in finalizing this valuable report.

Sincerely,



Debra Lochner Doyle, MS, CGC
State Genetic Coordinator
Manager, Genetic Services Section

Cc: Jan Fleming

Goodwin, Suzanne (NIH/OD)

From: KEVIN DROZDOWSKI [kd226@msn.com]
Sent: Friday, May 06, 2005 1:19 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comments on Coverage and Reimbursements of Genetic Tests and Services

Dear Ms. Goodman,

I would like to submit comments regarding the draft report on Coverage and Reimbursement of Genetic Tests and Services. I have cited the areas commented in the first sentence of each paragraph. If you have ay questions regarding my comments, I can be reached at kd226@msn.com. Thank you for your time.

Sincerely,

Kevin Drozdowski

1. (These are comments on recommendation in blue box on page 26) There does appear to be a need for appropriating a group or body to develop a set of principle to guide coverage decision making for genetic tests. According to this report, the uses of technology assessments play an important role in coverage decision making for genetic tests. Some insurance companies use their own technology assessment to make their assessments and other companies hire out companies to evaluate the situation such as Blue Cross, ECRI or Hayes Inc. Although, the criteria that are used at the Technology Evaluation Center at Blue Cross and Blue Shield are sound ones, there is always the risk of costly litigation between the private insurance companies, hospitals and the insured. A task force could help identify gray areas that could lead to litigation. This task force could clarify what should be covered. Also, they should be responsible for trying to identify ways to encourage private companies to find more accurate and less costly ways of testing. The government could consider providing incentives to those companies that follow the guidelines of the taskforce. Certainly, we should only be testing for diseases where there are current treatments.

2 (These are comments on recommendation in blue box on page 27) Private companies should be very clear and define specifically what they are going to cover and not going to cover. The standardization should be based on sound scientific evidence. This will benefit both the business ad the consumer. The consumer will be informed of what sort of tests will be covered and those that won't be covered. The consumer can benefit by making a more informed decision when choosing a medical plan. Sometimes, consumer demand can influence coverage decisions. Today, people are bombarded with health information. They see it on the television, hear it on the radio or more commonly find out health information on the Internet. Hidden within all of this health information are advertisements for certain health products or services. This maze can leave the consumer ill informed or at least confused. This has led to coverage of tests that should not be covered because of lack of sufficient evidence to support coverage of such tests. Private companies with clearly defined parameters can help make consumers make informed decisions. I can think of nothing more important than the children. Wherever and whenever possible we should take extra care in assuring that that the children are receiving the best possible care. The cost of preventative measures can be much less expensive than the treatments. Genetic Cockling Services cost 20 to 50 percent less than a physician would cost. It could save families heartaches and companies monies to prevent future treatable diseases.

3. (These are comments on recommendation in blue box on page 30) I agree that there should not changes to the current system. Most of the decision-making regarding Medicare coverage relies n 36 contractors around the country. The purpose of dividing into regions was to allow Medicare greater flexibility in responding to geographical variations in the types of genetic testing that is done. While I agree that everything should be done to balance out and make sure genetic testing is done the same across the board, it should be noted that it is entirely possible that you have a greater demand on specific types of genetic tests that maybe prevalent within certain populations. Areas that have greater concentration of populations that may warrant a certain type of test should not be denied that test on he basis of it being too expensive to test everyone on the interest of equity. Broadcast testing of all possible genetic disease is not feasible. Therefore, certain test may not be used based on their frequency or degree of lethality. Using the 36 regions that are currently in place can assure the potential regional variations that may occur.

4. (These are comments on recommendation in blue box on page 32) Predispositional genetic tests and services that provide preventative service to Medicare recipients should be covered under Medicare. However, I have some reservations regarding broadcast testing for genetic diseases to patients who have no current signs or symptoms. Medicare needs to prioritize the type of predispositonal genetic tests and services it will cover under Medicare. When prioritizing, Medicare should consider the severity of the disorder. It might not be cost effective to test for genetic diseases that do not have a lethal component or have relatively little negative effects. It may worth considering the frequency of the occurrence of a particular disorder. I realize that this may seem cruel. However, we have a set some limit on what Medicare is going to cover. I feel that it is appropriate to what accounts to genetic screening for Medicare beneficiaries who lack signs, symptoms or personal histories of illness. However, I would use caution with regards to the types and amounts of these tests that will be covered. The cost could get out of control. It would be fruitful to look at some real numbers regarding costs of these tests to better determine Medicare coverage.

5. (These are comments on recommendation in blue box on page 34) Medicaid coverage for genetic testing can vary from State to State. This can lead to a disparity in the types and amounts of genetic tests that Americans receive. If you live in a generous State where more benefits maybe offered, there could be more coverage of genetic screening and testing. While I agree that it is important to broadly disseminate information to the States such as guiding principles that serve as coverage decision-making. I am unsure how that resolves the issues where a State deems a procedure to be covered as legal such as family planning that can lead to a State-sponsored abortion. Is the Federal government going to simply tell what principles it wants or will it translate into a mandate?

6. (These are comments on recommendation in blue box on page 45) I would agree that the disparity that exists between payment schedule and cost of a procedure should to be addressed. Private companies should not have to pay a greater cost for a procedure than it actually cost less to perform. However, they should have to reveal the cost of old tests that have been made cost effective. How much money have these private companies made over he years by charging the same constant rate for a procedure cost far less to perform with modern technology? Both of these values should be quantified as part of an investigation into these cost disparities.

7. (These are comments on recommendation in blue box on page 52) Competition is a key element to assure lower costs. It is important for labs to be able to be fully reimbursed for the services that they provide. If labs cannot make enough profit to stay in business, then you will create a couple of problems. The first problem would be access to genetic tests. If there are fewer labs to run tests, then there will be a backlog of tests because there are not enough labs to perform these tests. Also, the limited number of companies that could run these tests could charge a premium for their service because there is no other option. This could lead to an increase in cost. In addition, companies may have to prioritize the services. In other words, uncommon or rare genetic tests could take longer or hard to acquire because the company is focused on more common procedures.

8. (These are comments on recommendation in blue box on page 54) It is essential that health professionals be informed about any type of new technology. Currently, there are many private companies that are marketing different types of genetic tests. Health providers that lack proper knowledge of modern genetic techniques could be lured by marketing strategies that are designed for profits and not in the interest of the government and its people. Also, it is essential that these health professionals are informed about these test so that the general public who may very well have no knowledge of genetics can have their falsehoods regarding a test removed. My concern is the cost of educating all of these health care professionals. Who is going to pay for the cost of educating these health care professionals? Will private companies pay some or all of the cost? If so, how much federal government money is going to be used to educate health care professionals? What is this education going to entail? Is it going to translate in to a degree or just a few survey courses?

9 (These are comments on recommendation in blue box on page 55) It is imperative that the federal government provides reliable and trustworthy information with regards to genetics, genetic technologies. It is essential that the federal government keep up with the fast and ever changing field of biochemistry. Genetic technologies are just braches of biochemistry. The Internet is filled with disinformation. All you have to do is choose a subject area and perform a google search. You will find disinformation about various topics. It would be critical to dispel myths regarding any new technology. As a biology teacher, I have some reservation about someone having my DNA on record. I have no grounds for my fears. However, an individual with no background in biology and/or biochemistry would probably have greater fears based on their misconception about genomics. It is essential that the public be offered a source of information that would clear any misconception regarding genetic testing and genetics. Federal government websites would be an excellent mode of disseminating this information. It would be wise to develop Public Service Announcements that could be broadcast through radio and television in order to inform the public of the new website and its contents. National Science Standards could be modified to reflect the new era of genetic testing.

Goodwin, Suzanne (NIH/OD)

From: KYDULUDE@aol.com
Sent: Thursday, May 05, 2005 4:31 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Recommendation Response

Kyle Dulude
Comments referring SACGHS Report:

1. "The Secretary should task an appropriate group or body to develop a set of principles to guide coverage decision making for genetic tests." (p. 26)

This recommendation is needed because the system needs a policy with rules. It is like taking blue prints for a house and then having a police officer on site to make sure the job gets down without breaking any laws. Principles need to be stated for consistency. These principles need then to be enforced as to provide direction. A group specific to this task would only seem respectable for the organization, thus promoting professionalism. Knowing that patient care fails to comply with evidence based guidelines, we need to construct guidelines that are non-negotiable and credible.

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.""(p. 27)

All information referring genetic testing should not be disclosed. Improving the health care of individuals occurs through a solid forward moving system. Let us keep in mind that each person, is responsible for their own health care. Parents need to do their jobs as parents and find care that is specific for their child.

If we are focusing on the pediatric population and whether it is relevant to apply care to all, would it not be efficient to disperse information to all (private and public) in hope that everyone may benefit in the end. Just like small business owners need to know the population to which they can handle, it is up to private payers to become informed of what is best for their patients.

3. "While not suggesting changes to the current system, SACGHS recommends that the Secretary encourages CMS to move forward with the implementation of Section 731..." (p. 30)

It seems that this recommendation is needed to keep genetic contributions towards health care up to date. By evaluating new local coverage, it serves as a system of checks and balances. This recommendation serves to maintain equality within the system. Being assertive and active seems to be the correct thing to do. Awareness and exposure is important for local coverage. It seems only fair that everyone across the country is supplied with the correct coverage.

4. "SACGHS recommends that preventive services, including predispositional genetic tests and services, meeting evidence standards should be covered by Medicare." (p. 32)

It seems that until someone is diagnosed with an illness, they should not take steps to cure it. The recommendation helps the prevention aspect of illness and allows people to diagnose earlier on to help the individual in the long run. It follows along the line of people giving other people the advice of not worrying about something until you are sure of it. It is easier to say "Do not worry about it, until you are certain" than to face the facts that something may be wrong. The quality of Medicare is reflective

upon preventive measures in this situation.

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." (p. 34)

If there is evidence of sound testing, then advice should be given to the appropriate people that need to make important decisions referring to the value of genetic testing. If the people who make health care policy are not informed of the benefits that genetic testing can provide, why would they go out of their way to take a chance on something and spend money on something that has no proof to benefit the patients. In this day and age, no one wants to just through money out the window. There are also enough scams and people trying to sell junk that and benefits that truly do not matter. If one can provide evidence of sound testing and prove its significance in the health field, let's get start being consistent with positive feedback this testing can have for patients.

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..." (p.45)

Let's face the fact that the cost of care and services fluctuates all of the time. When you buy something that is new or something that has just hit the market, you are going to pay more. Over time, something that cost so much may cost half as much because there are more distributors or the fact that research shows that something better has come along. The recommendation in this situation follows the theory of informing the public of the service first and then worrying about making up the cost later. From a business aspect, you can not market a product or service, if no one knows about it. Care would only seem reasonable if it was appropriate.

7. SACGHS recommendation regarding genetic counseling. P.52

The recommendation would help establish professionalism concerning genetic testing and providing qualified or certified individuals to properly instruct patients. The field needs qualified workers. I feel that it is important to recognize the educational component and the competency of individuals providing this service. People may feel more comfortable spending the money for genetic testing once they feel they are dealing with competent individuals who full heartedly spent a life time researching the medicine they are practicing. Genetic counseling may currently be a field many just are not aware of. I feel that once the public is aware of the service and the fact that qualified individuals are there to guide the process and show its relevancy, then everyone will receive the benefits from there own perspective.

8. "...the Secretary should develop a plan for HHS agencies to work collaboratively with state, federal and private organizations to support the development..." (p. 54)

The National Health Information Infrastructure is like Education in America. Students are expected to pass standardized tests and as a result, will not graduate if they do not. Teachers, consequently, are responsible for the student's success. There is talk that stipends will now be given out to those teachers that have the highest student success rate. Therefore, the education system seems to be toughening up the standards for those who work in the field. Everyone involved in an education system is affected by the governing standards provided by the state, which responds to government policy. The president's No Child Left Behind Act (NCLB) was set forth so that no child graduates who is illiterate and incompetent. The act was set forth to diminish the concept that students can be pushed along, without

mastery of any material. The policy was put in place to help students that are incompetent. Just as the president is trying to show the relevance of education and its value to better America, someone needs to show the relevance of genetic testing and its value in America.

9. "The secretary should leverage the HHS resources to develop and make widely available reliable and trustworthy information about family history..." (p. 55)

The word needs to get out, genetics is taught in high school classrooms, yet it is not received well by the public because of the way it is presented, partially by the media. The media states "Stem Cell Research..." was approved or disapproved by this party and that one, as if it were a comic strip. The media is making it a debatable topic, one of ethics and morality. It is taking on the form of a religion, in which some believe in it and some do not.

Health care consumers and providers need to have success stories and informative forums to show reliable and valid data referring the benefits of genetic testing. Although many would like to believe that people do all they can for prevention, the fast pace society we live in usually results in the person treating or responding to a certain medical condition after the fact they have been diagnosed. It will become harder and harder to prove genetics role in the health care system simply because the cost of health care seems to be on the rise. Many people seem to find jobs that have desirable health plans. To add another dimension to it will raise the cost. It will become the consumer's choice to pick one plan over another. If the consumer is unaware of the value of genetic testing, then why would they want to spend there money on that option.

Goodwin, Suzanne (NIH/OD)

From: Erickson, Etta [eerickson@healtheast.org]
Sent: Thursday, May 05, 2005 7:16 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Reimbursement for the professional services of a certified Geneticist

We have developed a Cancer Genetics Counseling Clinic as a service to our community. We have two qualified counselors who each see patients referred to the clinic (by surgeons and primary care physicians) for risk assessment related to breast, ovarian and colon cancer. Patients are educated and evaluated, and recommended as appropriate for a referral for testing in consultation with their physician. A complete report is dictated by the Geneticist and becomes part of the patient's record.

One f our two providers is a MSN, AOCN, Oncology Clinical Nurse Specialist (Master's prepared nurse with additional coursework and certification in cancer genetics), and is a credentialed provider. We are able to charge her professional fees as a credentialed provider.

The second provider is a Certified Geneticist with a Master's degree in genetics. We *cannot* credential her as a provider because Geneticists are not widely recognized by third party payers as qualified health care professionals. We can charge only a facility fee which offers far less reimbursement that a formal consult would.

Genetics is fast becoming an integral component of quality cancer care. Now is the time for trained geneticists to be recognized as the qualified health professionals they are.

Etta Erickson, System Director

HealthEast Cancer Care

St. John's Hospital

1575 Beam Avenue

Maplewood, MN 55109

(651)232-3172

(651)864-2532

eerickson@healtheast.org

A Passion for Caring and Service.

May 2, 2005

Maria U. Griffin

Public Comment on Coverage of Genetic Tests and Services

From the standpoint of being a mother, daughter, science teacher, and taxpayer I would like to make the following comments relating to the potential recommendations in the draft report titled, " Coverage and Reimbursement of Genetic Tests and Services".

1. **" The Secretary should task an appropriate group or body to develop a set of principles to guide coverage decision making for genetic tests."** Pg. 26

I wholeheartedly support the concept that there must be guidelines regarding coverage decision making for genetic tests. We are living in a Biotechnological age and medical coverage must reflect this. As stated in the recommendation "...identify criteria to help determine which types of categories of genetic tests should be covered, which should not be covered, and which fall into an uncertain gray zone" needs to be as explicit as is possible, yet at the same time allow for modifications and updates in a **timely manner.** The terminology "Uncertain gray zone", I believe, is ambiguous and needs to be qualified as to what determines uncertainty. I would also like to see some clarification regarding "Economic evaluation/cost effectiveness". What exactly does this mean and does it take into account high risk individuals? In other words would the cost of a test supersede the potential benefit of early detection of a genetic disorder regardless of risk or would the risk factor based on a family's history determine whether or not the genetic testing would be covered? In my opinion, these types of scenarios must be addressed in the principles.

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."** Pg. 27

Once again we are dealing with ambiguity. What specifically is meant by benefits and populations? Are we looking at the population on a national level, by ethnicity, gender, age, sex, etc.? By prevention component are we referring to genetic counseling and/or prenatal testing? In the case of prenatal testing what effects will results have on the current laws regarding pregnancy termination?

What I find disturbing about this recommendation is actually the remainder of the recommendation. **"Although standardization of coverage decisions using best scientific evidence across public and private sectors is ideal (see Recommendation 1), private payers should be supported with the necessary information to make their own coverage determination about these tests and services relative to the populations they serve."** The recommendation in itself looks like a "rider" that has been attached to a Congressional Bill. The two aspects of Recommendation #2, need to be addressed separately. I also do not see how genetic tests and services in pediatrics and preventative testing would not be addressed in Recommendation #1.Lastly if there is to

be differences between Medicare Coverage and private sector health insurance plans, then "population" needs to be fully aware of what the differences are.

3. " **While not suggesting changes to the current system, SACGHS recommends that the Secretary encourages 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.** Pg 30

Why not suggest changes? They are long overdue!!!!! There is absolutely no reason why coverage under Medicare is not consistent throughout the country. Regarding health care, (genetic, testing included), Medicare coverage needs to be consistent. For example, I live in Massachusetts and if I was covered by Medicare, I should expect the same coverage even if I moved to California. **Modernization** is the key word in this recommendation. It is inconceivable to even discuss Genetic Testing and Services without modernizing the entire Medicare system.

4. " **SACGHS recommends that preventive services, including predispositional genetic tests and services, meetings evidence standards should be covered under Medicare."** Pg. 32

Based on the current standards as described in this draft on pages 30-32, I fully support this recommendation. The current policy which states " Tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered except as explicitly authorized by statute" is not taking into account high risk based on family history, which is very important in presymptomatic genetic testing. Much of the information gained in genetic testing is based on family histories of disease, so the policy of family history of disease not meeting Medicare's "reasonable and Necessary criterion", is unreasonable. The prevention component, risk assessment, early diagnosis, severity of condition, age of onset and possible treatments are major parts of the Human Genome Project, and thereby necessitate inclusion in Medicare coverage through preventive services including predispositional genetic tests and services including counseling.

5. " **The Secretary should broadly disseminate to all states information about 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."** Pg.34

Although I strongly disagree with the reality that a state's fiscal soundness may be the determining factor regarding coverage of genetic tests and services, I cannot see this aspect of the draft changing. As a nation we operating "in the red", so it is obvious that the states end up having to have a balanced budget not to further deplete federal monies. It is essential that the most up-to-date and accurate information regarding genetic testing

and services be available to all states. This in accordance with recommendation #1 should hopefully foster a program which will make sound decisions that take into account the individual's need for genetic testing and/or counseling and that no one's life is ever endangered due to lack of funds.

6. " **In many cases, payment rates for genetic tests are lower than the actual costs 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 genetic test CPT codes through its inherent reasonableness authority."** Pg. 45

The issue being addressed here is reflective of the overall disastrous state of healthcare affordability in the United States. U.S. citizens are buying their medications outside of the country and traveling abroad to receive excellent, yet affordable healthcare. Mismanagement of Medicare funds, kickbacks, payment for services not provided, and corruption are just some of the issues that need to be resolved. Caps need to be placed on costs of tests and services rather than caps on payment rates. The Secretary should be able to determine what the "caps" should be based on the most current information. Suppliers should not be able to charge beyond the cap. If they do so, they will no longer be able to be a part of the program. "Legally" robbing from the American public by charging exorbitant fees, simply because a service provider knows they are only one of a limited number of suppliers, is unacceptable.

The reasons stated in the proposal which may initiate "inherent reasonableness" are a good start but certain points need to be revised. "There may have been increases in payment amount for a service that cannot be explained by inflation or technology". Remove this!!! The explanation is greed. If a provider is charging in excess of the payment schedule, than it becomes the responsibility of the provider to provide **substantial** evidence for the fee. In the meantime, service **cannot** be denied to the individual seeking the service based on payment discrepancy. As long as HHS stays current on the technology, the costs of that technology, and adjusts payment as is necessary there will be no issues with payment amounts being "grossly higher or lower than production costs."

7. " **SACGHS recommendation regarding genetic counseling"** Pg. 52

I fully support the recommendations as they are written. The detailed explanations of these recommendations in the draft take into account that Biotechnology is still considered a "new" and ever changing field of healthcare. They also recognize that incentives may be needed to reduce costs of testing and that the number of professional in the genetic field may currently be limited, but is growing. The billing process is difficult to understand, possibly because I am not in the health-care business. I sincerely hope that those that are understand this system, since recommendation #7 appears clear enough and should not be encumbered by a complex billing process.

8. "**...the Secretary should develop a plan for HHS agencies to work collaboratively with state, federal and private organizations to support the development, cataloging 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." Pg. 54

Finally it appears that there is a proactive plan rather than a reactive one. Kuddos to the draft!!! Genetics and genomics are ongoing sciences, in a constant state of change. Provider education and training is a must regarding the decision making process, coverage and reimbursement of genetic tests and services. Without provider education and training the changes and upgrades this document is trying to provide will not become a reality. Ignorance will only lead to chaos and will undermine the benefits of the testing and services.

9. " **The Secretary should leverage the HHS resources to develop and make widely available reliable and trustworthy information about family history, genetics, and genetic technologies to guide and promote informed decision making by healthcare consumers and providers."** Pg. 55

This is walking a very fine line regarding patient confidentiality. I agree that the public needs to be educated and that the information must be reliable and accurate. This information must also be accessible, but we must also make sure that the confidential medical histories of patients and their families are never compromised. Informed decisions by consumers and providers are the only decisions that should be made, so overall I am very supportive of this recommendation.

Steven Gundersen
Final Exam
Human Genetics 500-501
Dr. Hoagland
5-4-05

1. "The Secretary should task an appropriate group or body to develop a set of principles to guide coverage decision making for genetic tests."* Page 26**.

I agree with this plan, a committee of persons with sufficient knowledge of the four components of evaluation should be assigned to gather and present a comprehensive guide for health coverage companies to use and follow in the arena of providing health coverage for genetic testing.

I also agree that the committee should include persons from the private and public sectors and of opinions that encompass the entire scope of current views on health coverage for genetic testing.

A strong committee is a current need as plateaus in research and development have been reached in areas of genetic testing that have proven to be valuable and worthwhile to the public in promoting and increasing the health standards in this world.

There is now a sufficient base of proven genetic tests that heath coverage companies need to err conservatively but at the same time recognize that there are health needs being met and improved by genetic testing where other types of therapies have proven inadequate and these doors to solving general and specific health problems need to be kept open.

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." Page 27

A person should have available to them every possible answer and option to their health concerns. If this includes new and advanced technologies beyond where there is sufficient research or too narrow a target area for sufficient research to have been completed, so be it.

All possible and the most current data on all genetic testing should be made readily available to all private sector health plans to allow for the best decisions concerning coverage determinations for all and any individual.

The "lead and follow" system of coverage determination by Medicare to the private sector will only inhibit the acceptance and validity of genetic testing and continue to ignore the research that shows the benefits to a public outside of the Medicare target public age of 65+. Private players need to be allowed to move in directions they feel fit to fill needs of those they serve.

3. "While not suggesting changes to the current system. SACGHS recommends that the Secretary encourage 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." Page 30

Private players again need to be privy to the most current and best data on all genetic testing to determine their coverage determinations. Medicare also should be encouraged to follow suit as well. But in the current system where Medicare creates the coverage policies used in the private sector, valid and beneficial genetic testing needs to be addressed and included to at least allow private and local coverage sectors the options to cover genetic testing they determine as beneficial but Medicare has determined to not cover.

By opening the door wider, we make the options better for the public, therefore making valid genetic testing more so, and streamlining, allowing, encouraging and setting the very best standards for all genetic testing knowing the research could be considered by Medicare as valid and available for coverage, keeping the research engines out there driving towards a goal so to speak and expanding the health options to the general public.

4. "SACGHS recommends that preventative services, including predisposition genetic tests and services, meeting evidence standards should be covered under Medicare." Page 32.

There is exhaustive date and research compiled on several hundred genetic tests that show a benefit in some way to the general public. These tests need to be included in coverage determination policies set forth by Medicare.

To deny valid genetic testing is only inhibiting the (sometimes best) health options available to the general public. There is of course the need to deal conservatively with any testing, but valid testing that passes evidence standards should by no means kept off the Medicare approved list. To deny genetic testing in the face of valid research and development only shows a lack of insight, want for advancement and a lack of open mindedness to testing devices that have been proven to work in they way they were meant to.

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." Page 34.

This should be done, as I believe it will encourage in the least the most secure and sound genetic testing to survive cut backs at the end of each fiscal year, and hopefully as more genetic tests prove themselves and the prescription of these tests becomes more common, states will gradually make more of these genetic tests a place on their permanent roster of items under their Medicaid package.

This will be a popularity contest of sorts of what the current trends in genetic testing will dictate the inclusion and survival of "fringe type" genetic tests in a state's year to year Medicaid package.

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 CPT codes through its inherent reasonableness authority." Page 45.

I should think that a slight profit should come from medical testing of any kind, as long as the profit is reasonable and conservative. Here there is a direct and obvious need for payment rates to match and rise slightly above the cost to run the genetic tests.

Making a service conservatively profitable will enable the medical facility to run under its own power and allow the most streamlined and optimal services to be provided to the public with no risk of shortcuts or shortcomings in the services which may put the public at risk of compromised testing services and consequences etc.

Also the promise of profitability only sweetens the goal of approval of new genetic testing research. The knowledge that some return will be seen by researching these tests and having these tests available at a medical testing facility will only encourage and popularize genetic testing to the general public.

7. "SACGHS recommendation regarding genetic counseling." Page 52.

Moral issues aside, genetic counseling is a powerful tool today in its ability to prepare and help guide individuals through health issues and risk potentials such as the potentials for traits passing to a child from parents or from parents and family to an individual. Genetic counseling is a service being utilized more commonly each year and there is a need for the governing rules over this service to be updated and streamlined to allow this service to continue to grow and maintain the high quality of service by receiving full accreditation in the way of full billing and reimbursement under health coverage by both Medicare and private and local sectors.

Therefore, I would agree that genetic counseling services who currently bill incident to a physician to be able to utilize the full range of CPT E&M codes.

This will help to keep a high quality of genetic counseling service, continue to push quality standards, and provide the general public a high quality product while being governed conservatively and efficiently.

8. "...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." Page 54.

Genetics and genomics are relevant. There is a vast amount of research and development and proofs today that genetic testing is a relevant and worthwhile pursuit and holds ground in the

medical community as groundbreaking and sometimes the best solutions to health issues in this world today. To inhibit the advancement of genetics and leave it on the fringes of the medical community is dangerous and unnecessary. Being conservative is mandatory, but testing that passes the standards set today should be encouraged and allowed to be within the scope of options to the public when it comes to current health issues.

Allowing genomic related testing into an accepted medical arena will only help further every single area of the medical world today, and as the human genome is further uncovered and understood, advances in the medical world are right behind.

9. "The Secretary should leverage the HHS resources to develop and make widely available reliable and trustworthy information abut family history, genetics, and genetic technologies to guide and promote informed decision making by healthcare consumers and providers." Page 55.

The general public will only benefit by having safe, secure and fully regulated genetic counseling available to them. And the general public will also benefit by having the most up to date data and information on family history, genetics and genetic technologies available to guide decision making processes and health therapy. The data and technologies are out there, available, it is now just the task of someone to take genetic counseling data and technology into validity and wide spread acceptance by making this health option available and user friendly for the consumer and health provider.

Genetics and genomics are a part of the future of medicine. They may never be the entire part of medicine in the future but I believe that it will be a large part of the future of medicine as technology and our understanding of the most base parts of the human body are studied and stamped "understood" by tomorrows researchers and scientists.

To even make the future of genetics and genomics possible, we need to alleviate the difficulties in providing health coverage for these types of testing and counseling, as well as make people aware of the validity of genetic testing and counseling and make this a viable option away from the poor stereotype it now seems to harbor in the moral sense of growing babies in test tubes and stem cell research techniques. By encouraging and governing genetic data, research, and testing, we will advance and continue to bring the highest quality health services to the general public.

* all quotations were taken directly from the Draft Report of the Secretary's Advisory Committee on Genetics, Health, and Society from their Public Comment Draft entitled, Coverage and Reimbursement of Genetic Tests and Services.

** all page numbers correspond to the page where the quotation or paraphrase is pulled from the Draft Report of the Secretary's Advisory Committee on Genetics, Health, and Society from their Public Comment Draft entitled, Coverage and Reimbursement of Genetic Tests and Services.

Goodwin, Suzanne (NIH/OD)

From: Cheryl Eileen Harper [charper@beaumonthospitals.com]
Sent: Friday, April 29, 2005 10:37 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comments on Secretary's Advisory Committee on Genetics,Health, and Society

Dear Ms. Goodwin,

This letter is to comment specifically on Recommendation #7 of this draft report. First, I want to congratulate this Committee on their comprehensive work on this document. I'm very much impressed with the amount of research and deliberation that obviously went in to creating this report and recommendations. While I agree with much, if not most, of the recommendations made by the Committee, I do feel that some changes be strongly considered. Please note that these are my personal comments and do not reflect the opinions of any larger organization or my employer.

I am an ABMG//ABGC certified genetic counselor, have been in practice for 19 years, and work for a large, private hospital in Michigan. I first would like to applaud the Committee's recognitiion that Master's trained genetic counselors are uniquely qualified to provide genetic counseling services, along with apprropriately trained and certified genetic nurses. However, I feel that the Committee's recommendation to for HHS to simply establish a mechanism to determine specific qualifications that non-physician genetic services providers should have in order to be able to bill for their services is inadequate for addressing who should qualify as genetic service providers for billing purposes. As your report clearly states, genetic counselors have unique training to be able to provide these services yet have difficulties in billing for services because they are not physicians and therefore cannot use consultative codes or bill "incident to" physicians since most are not able to become licensed. This issue has a tremendous impact on public access to genetic counseling services since many hospitals will not be able to employ genetic counselors if there is no mechanism to create revenue from their services. Many genetic counselors' salaries are supported in whole or in part by grant funds because employers will not committ their own dollars to a service that will not support itself financially. I have run into this myself and experienced the possibility of loss of employment for this very resason. I know that many other genetic counselors across the country are in this same situation. If there is no way to bill for our services, employers cannot afford to hire us and consequently, there will be less qualified genetic counselors available to provide these important services. I strongly urge this Committee to recommend that Master's trained and ABMG/ABGC certified genetic counselors be recognized as qualified providers of genetic counseling services and be allowed to bill independently for these services. Additionally, I strongly concur we the remainder of this Committee's recommendations regarding billing and reimbursement for genetic counseling services.

Thank you for your consideration.

Sincerely yours,

Cheryl E. Harper, MS, CGC
Genetic Counselor
William Beaumont Hospital
Royal Oak, MI 48073
(248) 551-0124
charper@beaumonthospitals.com

THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON
MEDICAL SCHOOL

DEPARTMENT OF PEDIATRICS
DIVISION OF MEDICAL GENETICS

6431 Fannin Street
Houston, Texas 77030

713 500 5763
713 500 5689 *fax*

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892
Email: goodwins@od.nih.gov
Fax: 301-496-9839

April 30, 2005

Dear Ms. Goodwin:

I am writing in regards to the SACGHS Draft Report on Coverage and Reimbursement of Genetic Tests and Services. I am a practicing genetic counselor/Ph.D. medical geneticist and a professor at a large urban university medical center. I am constantly being confronted with issues related to comprehensive provision of medical genetics services, and have to deal with various barriers placed upon my practice by reimbursement limitations for the services that we provide.

I am enthusiastic about SACGHS's efforts to elucidate the importance of medical genetic services and the obstacles that medical genetics practitioners including genetic counselors face. I want to encourage your committee to consider the following revisions to your draft in preparation of your final report:

1. Genetic counselors are **not** statutorily eligible to bill Medicare for the services we provide. While this point can be inferred from the text of your draft as it stands, I believe that it is in the committee's best interest to make this point specifically. Many practitioners of genetics (i.e. MD geneticists, nurse geneticists) are recognized providers per Medicare; making the point that such a large segment of providers, namely genetic counselors, are not, will help to seal the gravity of the reimbursement issues you discuss.

2. The statement regarding establishing a mechanism to later determine which providers have the credentials necessary to be considered as reimbursable providers of genetic counseling services should be inclusive of all providers of genetic counseling services. I appreciate the advisory committee's desire not to leave any potential

providers out of its recommendations. However, genetic counselors, in particular, already have the appropriate credentials and training necessary to provide genetic counseling services. Given that we do comprise such a large percentage of genetic health care providers, I feel that our profession and its credentialing process should be particularly recognized. Genetic counselors should be recognized as reimbursable providers, with the caveat that other eligible providers should be further identified and included in future efforts.

Thank you for undertaking the effort on behalf of all genetic counselor providers. It is important to note that the final report has the potential for impacting decisions that are made both by the government and by private payors. This is very, very important and special attention needs to be made to the final report. Genetic counselors provide a large percentage of medical genetic counseling and reimbursement is necessary. Thank you for you kind attention to this matter.

Sincerely,

Jacqueline T. Hecht, Ph.D.
Professor, Division of Medical Genetics
Co-Director, Genetic Counseling Program
Department of Pediatrics

Goodwin, Suzanne (NIH/OD)

From: Karen Heller [karenheller@swbell.net]
Sent: Thursday, April 28, 2005 5:15 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: SACGHS report - public comment

Dear Ms. Goodwin:
As a genetic counselor in practice for over 20 years, I would like to make the following comment regarding the draft report of the SACGHS:
I think the document is an excellent summary of the issues. Although implied in the document as it is currently worded, I think the following should be explicitly stated:
Genetic counselors, currently not recognized as Medicare providers, are trained and credentialed to provide genetic counseling services. Therefore, mechanisms should be established for genetic couselors to be reimbursed for these services by Medicare, Medicaid and private insurers.

Thank you
Karen Heller, MS, CGC
Certified Genetic Counselor

Karen Heller, MS, CGC
karenheller@swbell.net

May 5, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin,

This is in response to the request for public comments on the draft report on coverage and reimbursement for genetic tests and services as per Federal Register/Vol 70, No. 63/Monday April 4, 2005/Notices.

While the desire to provide coverage is a noble one, I am concerned that in order for an individual to receive coverage that he may be **required to disclose his and his family's "personal history" or family history of a particular disease** via the internet or through some other means that will impact that individual's privacy and that of his family. See Sections 4 and 9 in the Federal Register as noted above.

Unfortunately, as evidenced by the implementation of the HIPAA medical privacy rule, it is very easy for the patient's decision-making power as to who should access his private medical information to now be at the sole discretion of the federal government and health care providers. If indeed genetic testing and information is the wave of the future, it is imperative that such testing and information be provided on a voluntary basis by the patient, and does not become a requirement by the government or health care providers in order to obtain medical treatment.

Further, as I stated in my testimony before the Subcommittee on Privacy and Confidentiality on February 23, 2005, in view of the rampant data breaches such as ChoicePoint and the Secret Service and many others, the government should not encourage citizens to post such private and sensitive information such as family health histories on the internet, nor should electronic medical records be required with such profound privacy breaches a reality. Also, in an individual providing his family's health history, he not only provides the potential for his own genetic profiling and discrimination, but that of his family members as well, who may not wish for such personal information to be disclosed.

Thank you for considering my comments.

Robin Kaigh
P.O. Box #8444
Cherry Hill, NJ 08002

EVANSTON
NORTHWESTERN
HEALTHCARE

Janardan D. Khandekar, MD
Louise W. Coon Chairman
Department of Medicine

Professor of Medicine
Northwestern University Medical School

Evanston Hospital
2650 Ridge Avenue
Evanston, Illinois 60201
(847) 570-2510
(847) 570-2905 fax

April 27, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin:

As Chairman of the Department of Medicine and an oncologist at Evanston Northwestern Healthcare, I am writing in support of the Committee's recommendations to Congress, especially #7, regarding genetic counseling services and reimbursement issues. I would, however, like to see a strengthening of some of the key issues.

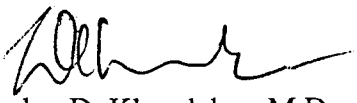
Our Center employs three ABGC-Certified Genetic Counselors in a clinical capacity and these counselors see approximately 60 appointments per month for conditions that affect adults. Four additional counselors are employed by the Department of Obstetrics-Gynecology. With the preparation time, counseling sessions, blood draws, disclosures and post-visit evaluations, having non-physician National Provider identifiers assigned to our Certified Genetic Counselors with the ability to bill independently is an urgent need. It would certainly increase access to our services if our counselors had the capability of billing independently of the physicians. At present the counselors need to supplement their positions with research studies to cover their salaries. Having the capability of billing would open the schedule to more appointments which would serve those in need of genetic counseling in a timelier manner.

Frankly speaking, our program and others around the country typically rely on the good graces of hospital administrators to absorb the uncovered costs of genetic counselors. In the current financial climate, this translates into very poor access for most patients because a genetic counselor cannot be employed in their community. This also puts existing programs such at ours at high risk of cutbacks. It is clear that overall demand for genetic services is high, that most physicians lack sufficient training and time to fill this need, and therefore that this need is unmet. Given that genetic counselors have the most rigorous training in the science and psychology of genetic counseling, it is absolutely essential that we support their specialty by making it feasible for them to survive as a profession. Indeed, the vacuum created by the lack of reimbursement mechanisms for genetic counseling services has begun to create a totally unregulated market for what is termed "genetic counseling" but clearly is not according to professional standards. I would therefore further advise that additional studies be done to assess other professionals who may not currently have as robust credentialing programs as do genetic counselors.

The State of Illinois has taken the first step in approving the licensing of genetic counselors and our counselors are ABGC certified. With these credentials I would like to request that the recommendations include a provision that these certified counselors should be considered as qualified providers with the ability to bill independently.

Thank you in advance for reading my comments.

Sincerely,



Janardan D. Khandekar, M.D.

JDK/lkm

Goodwin, Suzanne (NIH/OD)

From: Shena Kuralowicz [kurbull474@yahoo.com]
Sent: Thursday, May 05, 2005 9:47 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Public input on Genetic Testing

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 coverage decision making for genetic tests." Page 26.

   The Secretary, along with advisors in the genetic field should develop a list of genetic test that should be performed or not performed keeping in mind that cases will vary from person to person. Categories of covered, noncovered and gray area genetic tests should be determined depending on a few issues. These concerns include the frequency of the genetic disease that occurs in one's family, the diagnosis and treatment of the disease and other factors that could affect the occurrence of inheritance such as environmental. I agree that before allowing genetic testing to be performed, the outcomes of the tests that are already being performed should be observed and reviewed for purpose and effectiveness.

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." Page 27.

   The genetic tests and services performed that have a prevention component should be looked at because not all individuals may want the outcomes that arise from genetic testing. Yet other individuals may be looking for more answers. For example, being able to uncover an untreatable disease through genetic testing may have the benefit of allowing the individual to plan accordingly yet this information may be something that they don't want known. This can allow for unhappiness to life (or over expenditure of life) and many forces could use this information wrongly; employers and insurance companies are a couple of examples.

3. "While not suggesting changes to the current system, SACGHS recommends that the Secretary encourage 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." Page 30.

I agree that a more consistent approach to Medicare coverage should be looked at and developed. Not allowing a specific form of genetic testing because of an individual's location of residence seems unfair and discriminatory. Both the national and local systems are needed to make final decisions because the national system should voice Medicare while the local system should be the voice of the people and individuals from the local system area should be included in helping make the final decisions. Also, in order to make a decision about genetic testing, the individuals involved should be educated in the area. Being educated versus unaware about the issue of concerns can change one's opinion whether it is for the better or for the worse.

4. "SACGHS recommends that preventive services, including predispositional genetic tests and services, meeting evidence standards should be covered under Medicare." Page 32.

Predispositional genetic tests and services as well as preventive services should be offered through Medicare. Testing for a genetic disease with no signs, symptoms, complaints, etc, is considered a screening and therefore not covered yet there are other "screenings" performed for various diseases and conditions. Drug screening, HIV screening and pregnancy screening are just a few tests that are performed and not always based on sign or symptoms but rather feelings and uncertainties. Allowing preventive services for genetic testing could prove to be beneficial to the individual later on especially when a disease has been identified. Allowing individuals access to genetic testing information and outcomes would also be considered in some individuals decision making on starting families and planning their lives and the lives of loved ones ahead of time.

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." Page 34.

The more information that the states have on genetic testing and services, they have a better chance of making a more beneficial decision for the people they service. Providing states with guiding principles would also promote a more consistent decision from state to state. By providing states with grants to use for genetic testing and other services (as long as the test proves worthiness) HHS would be encouraging the states medical programs to perform genetic services. By providing grant money for genetic testing and services, hopefully would allow Medicare to offer coverage for testing every year instead of determining coverage from year to year and on an individual's needs basis.

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 CPT codes through its inherent reasonableness authority." Page 45.

One of many unnecessary stressors that patients undergo during diagnosis and treatment is "will I be covered under my insurance". Then patients wonder how they will pay for the care and frequently opt for no care at all because they cannot afford it. Patients should know beforehand if the procedure or tests that they are about to undergo will or will not be covered under their insurance plan. Patients and families should not have to go through the surprise that insurance

company's spring that coverage will not be provided. I would like to see the government pick up remaining costs of genetic testing and other services. This is one of the areas that I'd rather see the federal money go to.

In addition to the coding system that insurance companies use, a specific genetic CPT code list should be developed. The coding system that medical facilities and insurance companies use seems to be lengthy and could be confusing. Geneticists should have a separate coding system for more clarity and for a higher chance of coverage. By having a separate set of codes, geneticists can have a more specific set of codes that applies to the services that they offer instead of being generic. Because the CPT E+ M coding system is so extensive and confound, training in how to use the system would be beneficial to the medical facility, insurance companies and to the patient.

7. SACGHS recommendation regarding genetic counseling. Page 52.

   Genetic counselors are indeed a significant part of genetic testing and genetic services. Who would better have the knowledge and expertise needed in the field of genetics? Geneticists study genes (how they function and mutations that occur), inheritance factors, and many other aspects of genetics. Qualified health providers should be allowed to bill insurance companies. Knowing that insurance companies will be billed for treatment would give patients a piece of mind and encourage them to use genetic counselors and genetic services. Genetic testing and services is expensive and patient payment could hinder treatment. A CPT coding system should be created for those in the genetic field who are providing genetic services.

8. ". . . 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." Page 54.

   In order to prepare health providers with the education and knowledge that is needed in order to appropriately treat patients, education should begin in school. Currently many of those in medical school don't seem to focus on and learn in depth about genetics. They brush by on diagnosis and treatment, not how and why disease and mutations occur. Knowing how and why creates a whole new view on genetics. There are formulas available for figuring out relative fitness, allele frequencies, genetic relatedness and many other important factors of genetics. In knowing how to do this, those working in genetics can provide a more accurate and meaningful prognosis. Another benefit of having properly educated individuals helping make the decisions about the genetic services that should be offered would be that they know what is valuable and relevant to genetic testing.

9. "The Secretary should leverage the HHS resources to develop and make widely available reliable and trustworthy information about family history, genetics, and genetic technologies to guide and promote informed decision making by healthcare consumers and providers." Page 55.

   Being with genetic education in grades K-12 would definitely create a firm foundation in knowledge of genetics. Many teachers and instructors do not explain genetics simply because of its complexity and underestimation of the ability of the students to learn and understand. For example, many think that brown eyes are dominant over blue but dominance of eye color deems to be more complicated. Teachers can have fun with genetics and give students a head start on a

rising new form of health care.

Those who want to research and learn about genetics and the serves available or soon to be available should be able to read up on the topic at an approved and or accredited web site, books, etc. Having the government oversee the available literature would provide authenticity and privacy.

Comments for each of the nine recommendations listed above should be at least one paragraph in length for a total of nine paragraphs. These comments should be forwarded to me via email and to:

Suzanne Goodwin at goodwins@od.nih.gov. Comments also can be sent or via facsimile to 301-496-9839 or by mail to:

Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892 (20817 for non-US Postal Service mail)

Goodwin, Suzanne (NIH/OD)

From: Leeth, Elizabeth [ELeeth@enh.org]
Sent: Wednesday, May 04, 2005 1:02 PM
To: Goodwin, Suzanne (NIH/OD)

Dear SACGHS Members,

In response to the recent Secretary's Advisory Committee on Genetics, Health, and Society draft report "The Coverage and Reimbursement of Genetic Tests and Services" I am pleased to have seen the inclusion of recognition of certified genetic counselors as healthcare professionals qualified to provide genetic services and for their services to be covered and/or reimbursed by payers. I would like to add that this qualification is innately tied to the American Board of Genetic Counselor certification process. This certification is critical in the quality control of genetic counseling services and should be a standard for genetic healthcare providers/employers and coverage/reimbursement by payers. I feel that it is important for you to please consider the addition of ABGC certification as a standard for genetic counseling services and billing/reimbursement into your recommendations.

Sincerely,

Elizabeth

Elizabeth Leeth, MS
Assistant Manager, Fetal Diagnostics
Evanston Northwestern Healthcare
Ph: (847) 570-1380
Fax: (847) 733-5087
Pager 847-434-(9108)

Goodwin, Suzanne (NIH/OD)

From: B. Lerner [mebnl@verizon.net]
Sent: Tuesday, May 03, 2005 9:42 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Secretary's Advisory Committee on Genetics, Health, and Society public comment

Dear Ms. Goodwin,

I am writing as a genetic counselor and current graduate student in the field of health outcomes research, to commend the work the Secretary's Advisory Committee on Genetics, Health, and Society has completed in the development of the Draft Report on Coverage and Reimbursement of Genetic Tests and Services.

The committee acknowledged that access to genetic testing and services is uneven throughout the country although research and time is proving both valuable medical advances. Unfortunately, until reimbursement for both is accomplished, access cannot begin to be addressed. One of the obstacles still facing the ability of genetic counselors to provide care to a great number of individuals is their inability to reimburse for services they render and the first step to overcome that is to recognize ABGC certified and/or licensed genetic counselors as qualified providers who should have the authority to bill independently. I would also suggest that GNCC genetic nurses be included in that category. My request is that the committee's report specifically includes a statement supporting that stand.

Thank you for this opportunity to provide comment on this document and for the considering of my request offered by the committee.

Sincerely,

Barbara Lerner, MS, CGC

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Barbara Lerner, MS, CGC
Genetic Counseling Program
Brandeis University
Waltham, MA 02454
Campus phone: 781-736-2336
Campus fax: 781-736-3107
Home office phone: 781-674-2683
Home office fax: 781-674-2683
Email: lerner@brandeis.edu

Goodwin, Suzanne (NIH/OD)

From: Paul K Marcom [marco001@mc.duke.edu]
Sent: Friday, May 06, 2005 11:10 AM
To: Goodwin, Suzanne (NIH/OD)
Cc: Robin H King; Adam Buchanan
Subject: Secretary's Advisory Committee on Genetics, Health, and Society Genetic Counselor Clinical Service Recs

Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Attn: Susan Goodwin

To The Committee Members:

I am writing to commend the Secretary's Advisory Committee on Genetics, Health and Society for its substantive recommendations on coverage and reimbursement of genetic testing and genetic services. As a medical oncologist with special training in genetics and Director of the Duke Comprehensive Cancer Center's Hereditary Cancer Clinic, I recognize the importance of thorough, comprehensive policy regarding this issue.

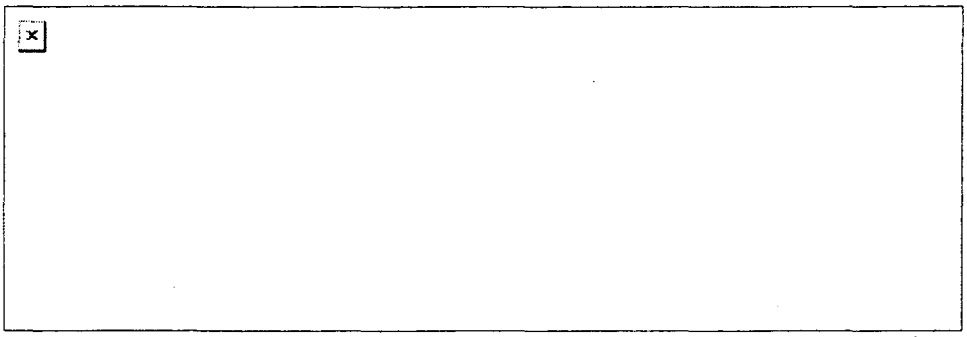
My one comment on the Committee's recommendations pertains to recommendation #7 (p. 52). Although I fully agree that qualified non-physician genetic counselors should be able to bill directly for genetic counseling, the recommendation is ambiguous regarding which non-physician health professionals should able to do so. I strongly suggest the recommendation be revised to state clearly that only ABGC-certified genetic counselors be recognized as qualified genetic counselors with the ability to bill independently for genetic counseling.

In my experience, only ABGC-certified genetic counselors have the unique training necessary to adequately counsel patients about the complex genetic, medical and psychosocial issues involved in genetic testing. I supervise one ABGC-certified genetic counselor and two ABGC-board eligible genetic counselors; all are vital to our clinic's provision of cancer risk assessment and counseling. Allowing them to bill independently would improve patient care in many ways, including: 1) allowing genetic counselors to perform outreach in underserved areas, in which the expertise to supervise genetic counselors rarely exists; 2) allowing them to devote more time to clinical duties, rather than having to supplement salaries with research funding; and 3) potentially offsetting other medical costs by helping patients enact cancer prevention and early detection.

The Committee has produced an impressive document; by incorporating the above suggestion I believe it can be even stronger.

Thank you for your consideration.

Sincerely,



P. Kelly Marcom, MD
Assistant Professor, Department of Medicine
Director, Hereditary Cancer Clinic
Phone (919) 684-3877
DUMC Box 3147, Durham, NC
Duke University Medical Center

Goodwin, Suzanne (NIH/OD)

From: mcpherson.elizabeth@marshfieldclinic.org
Sent: Wednesday, April 27, 2005 4:03 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Genetic Counselor Reimbursemen

Dear Ms. Goodwin,

I am a Board Certified Clinical Geneticist with 25 years of clinical experience. I am writing this note personally in support of reimbursement for the daily work of genetic counselors upon which I have depended throughout my career.

First, I would like to thank you and the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) for the work that has been done in putting together draft recommendations on coverage and reimbursement. Because your recommendations will be reviewed by others and possibly "watered down" during the political process, I think it is vital that the initial recommendations be as comprehensive and definitive as possible. Specifically, in recommendation #7 regarding genetic counseling services and reimbursement issues, I am asking that the committee more clearly state the recommendation that ABMG certified genetic counselors be recognized as qualified providers who have the authority to bill independently.

Genetic counselors are highly trained professionals who perform valuable services that would otherwise have to be performed by ABMG certified physician Clinical Geneticists like myself. Because I have genetic counselors working with me, I am able to offer services to more patients and to do more outreach in underserved areas than would be possible if I had to do all the history taking and genetic counseling myself. Unfortunately many institutions are unwilling to hire enough of these skilled certified professionals because there is no reimbursement available for their services. With predictions of a shortage of physicians entering Clinical Genetics in the future, and continuing cost-cutting through all levels of health care, unless reimbursement becomes available for genetic counselors in the near future we will see a serious decline in availability and quality of genetic services throughout the country. I left a previous position becasue I could no longer provide adequat! e services to my patients when my genetic counselor support was withdrawn. I am certain other physicians will do the same unless support for genetic counselors through fair reimbursement for their services becomes available.

I also support the remainder of the recommendations regarding genetic counseling service coverage and reimbursement, including the reimbursement of prolonged service codes both for direct and incident to billing, and the inclusion of non-physician health care providers eligible to directly bill health plans as eligible for national provider identifier.

Sincerely,
Elizabeth McPherson MD

FOX CHASE
CANCER CENTER

May 2, 2005

Secretary's Advisory Committee Genetics, Health, Society
NIH Office of Biotechnology Activities
6705 Rockledge Dr.
St. 750
Bethesda, MD 20892

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

This letter is from the perspective of both oncologists and genetic counselors at Fox Chase Cancer Center regarding recommendation # 7 for billing and reimbursement for genetic counseling services. We appreciate that the issues of genetic counseling billing and reimbursement were addressed in the drafted document. We realize that the issue of billing and reimbursement may not be directly influenced by this document. However, it may serve as a guide for third party payers, and we request our comments be reviewed for this purpose.

The drafted document should define "qualified providers" with regard to performing genetic services. A blanket statement of "qualified providers" without criteria may lead to future confusion regarding this issue. It should clearly state that American Board of Genetic Counseling (ABGC) and/or American Board of Medical Genetics (ACMG) certified genetic counselors have the authority to bill along with other providers who have met comparable criteria. These exact provisions for billing by non-physician providers should be addressed by the respective professional organizations with ABGC criteria serving as a template for other organizations. It is clear that ABGC has criteria already in place for determining competency including a board certification exam along with a log of cases from a ABGC accredited training program. This strategy has been used for other professional groups, including physicians. For example, the physicians have to take a board examination as a means of demonstrating competency for a particular specialty. The service of genetics should be held to the same standard to benefit patient care. At this time, the ABGC and ACMG are the only organizations that have

developed board certifiable standards for genetic practitioners, which include clinical geneticists (MD's) and genetic counselors (Masters level). These existing standards should set precedence for all other professional organizations. Use of the existing ABGC standards was a key point suggested by more than one of the (non-genetic counselor) committee members during the public webcast of the hearings held in March 2005. Therefore, use of these standards should be similar across professional organizations for both current providers and those that will be added to meet the anticipated future demand for genetic services. The necessity of this clarification also stems from the primary point that the standards of qualification should not be made more flexible for the sole purpose of increasing access to genetic services and thereby compromising the integrity of patient care. In fact, these standards will allow those interested in pursuing genetic competency a means to achieve both competency and potential reimbursement for their institution.

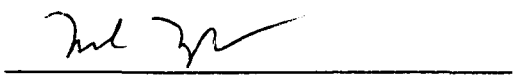
Billing and reimbursement will increase both access to genetics care and be a more cost effective use of healthcare dollars. First, it will increase access because it will allow patients to use their insurance for these services and will increase visibility for the genetic counseling services making them more accessible to patients. In light of the anticipated shortage of the genetics workforce, billing and reimbursement will increase the number of genetics providers that a given institution can hire since they will receive reimbursement for the genetic counseling services. We have to realize that much of the healthcare workforce is in short supply, including nurses whose base is being tapped into to provide genetic services. At this point, without a professional organization being allowed to set precedence, there will be no effective means to gauge the quality and number of providers until it is too late. If genetics is to be successfully integrated into mainstream medicine, then there needs to be a way for patients to receive genetic consultation, which will more frequently be from a genetic counselor (majority of the genetic provider sector). The lack of billing capabilities by appropriate genetic providers will allow for a system of medical care where genetic services are provided by those that are not qualified and will cause an increase in the already existing pool of malpractice suits (Offit et al JAMA 292(12), 2004).

Billing and reimbursement of genetic counseling services will also provide a means for curbing and streamlining testing based on scientific rationale. It will assure that needless inappropriate tests are not ordered and then misinterpreted. Currently, there is a disincentive for patients to pursue high quality genetic counseling, because this service is not billable to their insurance. Therefore, they may choose to go to their primary care physician, because insurance will pay for that visit, but they may not receive the same level of care.

Finally, genetic counselors do function relatively independently in certain settings including the cancer genetic setting and prenatal genetic setting. The physician and genetic counselor are part of a multidisciplinary team of professionals, each providing a unique service to the patient and their families. For example, at Fox Chase Cancer Center, the genetic counselor and/or nurse provides initial risk assessment. The genetic counselor then follows the patient if they proceed with genetic testing, and the disclosure of genetic test results is done with a genetic counselor and physician present for medical management recommendations. Therefore, this standard of care will be upheld in the future only if billing and reimbursement of genetic counseling services (by a defined qualified provider) can be endorsed.

For the above reasons, the Fox Chase Cancer Center medical oncologists and genetic counselors strongly recommend both that genetic counselors be considered qualified providers that can bill independently, and that the ABGC serves as a prototype for other professional organizations interested in attaining qualified provider status.

Sincerely,



Neal Meropol, MD
Senior Member
Director, GI-Tumor Risk Assessment Program
Fox Chase Cancer Center

Mary Daly, MD, PhD

Director, Margaret Dyson Family Risk Assessment Program

Director, Cancer Control Science Program

Fox Chase Cancer Center

Hetal Sheth, MS, CGC

Genetic Counselor

Fox Chase Cancer Center

Candace Peterson, MS

Genetic Counselor

Fox Chase Cancer Center

Cary Armstrong, MS, CGC

Genetic Counselor

Fox Chase Cancer Center

MICHIGAN CENTER FOR GENOMICS AND PUBLIC HEALTH

UNIVERSITY OF MICHIGAN SCHOOL OF PUBLIC HEALTH

M4157 OCBPH SPH II 109 S. OBSERVATORY ANN ARBOR, MI 48109-2029
TELE: (734) 615-3141 FAX: (734) 936-0927 E-MAIL: MOD@UMICH.EDU

May 6, 2005

SACGHS
NIH Office of Biotechnology Activities
6705 Rockledge Dr., Ste. 750
Bethesda, MD 20892

To: The Secretary's Advisory Committee on Genetics, Health, and Society

Let me congratulate the Secretary's Advisory Committee on Genetics, Health, and Society for preparing such an extensive report on coverage and reimbursement in the genetics area, information which is much needed but is typically difficult to document in a reasonable consolidated manner. I am sure SACGHS's report will be widely utilized in the future.

I am pleased the report contains a section on reimbursement of genetic counseling services, an area which needs attention as genetic counselors are often not fully reimbursed for the hours of service they perform. I would also like to bring to your attention several documents which comparatively describe insurance coverage for a variety of genetic services from testing to counseling, and which you may wish to include or cite in your report:

- Andrews LB, Fullarton JE, Holtzman NA, Motulsky AG, eds. (Institute of Medicine). Assessing Genetic Risks: Implications for Health and Social Policy. Washington, D.C.: National Academy Press; 1994: 234-46.

- Bernhardt BA. A Survey of Reimbursement for Cystic Fibrosis Carrier Testing. J Genetic Counseling 2(2); Jun 1993: 69-76.

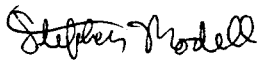
- U.S. Congress, Office of Technology Assessment. Genetic Tests and Health Insurance: Results of a Survey – Background Paper, OTA-BP-BA-98. Washington, D.C.: U.S. Government Printing Office; 1992: 25-9.

- U.S. Congress, Office of Technology Assessment. Cystic Fibrosis and DNA Tests: Implications of Carrier Screening, OTA-BA-532. Washington, D.C.: U.S. Government Printing Office; 1992: 179-84.

I have not obtained any more recent comparative data looking at the various types of insurance categories and coverage provided, but will certainly send any new material on

to the Committee should it appear. I am mailing the Committee copies of the above referenced pages. My best wishes to the SACGHS in its incorporation of public comment, and in its final preparation of the Report.

Sincerely,



Stephen M. Modell, M.D., M.S.
Dissemination Activities Director,
Michigan Center for Genomics and Public Health
M-4157, OCBPH, SPH-II
109 S. Observatory
Ann Arbor, MI 48109-2029

7

Financing of Genetic Testing and Screening Services

77

The cost and financing of genetic testing and counseling have had a profound impact on access to these services in the United States (OTA, 1992b). No matter what aspect of genetics is discussed, it is almost impossible to keep the discussion from turning to issues related to financing of genetic testing services, in particular the role of health insurance in genetic testing and counseling.

The United States is the only developed country in the world without a social insurance or statutory system to cover basic expenses for medical services for most or all of its population (Fields and Shapiro, 1993).[1] This creates problems of access and equity, especially for low-income or high-risk individuals who are self-employed, work part-time, or are employed by small businesses and who may not be able to afford or obtain health insurance. More than 36 million people are without health insurance coverage in the United States (EBRI, 1993, p. 1).

Current activities in health insurance reform may obviate some concerns about health insurance discrimination related to genetic testing and the use of genetic information. The Ethical, Legal, and Social Implications Program (ELSI) Task Force on Insurance and Genetic Testing (ELSI Insurance Task Force, 1993)[2] has already submitted its concerns to President Clinton's health insurance reform committee. Health insurance reform proposals will need to be evaluated to determine whether they adequately protect genetic information and persons with genetic disorders from discrimination and other potential social, legal, and ethical harms related to health insurance and the use of genetic information (see Chapter 8).

Even for those who have health insurance, coverage for most preventive, screening, and counseling services may be excluded. These limitations of U.S. health care coverage particularly affect genetics services, which have an impor-

Assessing Genetic Risks: Implications for Health and Social Policy

tant counseling component. As discussed below, insurance reimbursement or other financing for genetic diagnosis, testing, and screening, and essential genetic counseling, is not generally available now in the United States.

Moreover, the committee heard testimony at its public forum that individuals whose insurance does cover some or all genetic services may be reluctant or unwilling to file claims for such services. They may fear that the information they seek might be used to evaluate and deny their future applications for health or life insurance coverage, or might lead to higher premiums or limited coverage. Because much coverage in the United States is employment based, people may also worry that their employer will have access to the information and use it (overtly or covertly) to discriminate against them (Fields and Shapiro, 1993).

Even the casual conversation of medical personnel, human resources staff, and others about genetic information may affect insurance coverage if such information is reflected in medical records or in the personnel system of self-insured companies. To avoid such impact on insurability, some genetic counselors report that they routinely advise their counselees not to seek insurance reimbursement because of the potential risk to future health and life insurance coverage for them and their families (OTA, 1992c). However, if the information is subsequently sent to primary care practitioners for follow-up care and entered in the patient's medical record, insurers may then have access to that information even if they did not reimburse for the test itself. Many people seeking genetic testing and/or genetic counseling now pay "out-of-pocket" for such services, either because they do not have insurance coverage for such services, or because they fear the consequences of having such information known to their insurance companies or to others. To keep information about genetic testing from reaching insurers, physicians are sometimes being requested to set up separate patient records (as is now sometimes done for records of treatment for AIDS or mental disorders).

When people do pay out-of-pocket for genetic diagnosis and testing, they often pay a substantial sum, especially if the testing requires complex linkage analysis. The cost of complex family studies involving linkage analysis ranges from $500 to $4,000, depending in part on the number of tests and the size of the family. The person seeking the testing must be able to pay the full costs of the testing for *all* relatives, or the testing may not be performed.

Direct DNA testing of individuals can be considerably less expensive; such tests now cost from $50 to more than $900 per test. Future costs for DNA tests could be even lower with automation and more widespread testing, and costs of $50 to $150 for a panel of six or more DNA tests are now being discussed; however, patents and royalties resulting from the patenting and licensing of genes and gene products have the potential greatly to increase the cost of such testing, as has already occurred in DNA tests for cystic fibrosis (Beaudet, 1992). These cost estimates for direct DNA analysis do not include any of the costs of interpretation, education, and genetic counseling prior to and/or following direct DNA testing (see Chapter 4).

Andrews LB, Fullarton JE, Holtzman NA, Motulsky AG, eds. (Institute of Medicine) Washington, D.C.: National Academy Press; 1994

Genetic counseling is generally not reimbursed directly by health insurers unless the counseling is provided or billed by a physician, although the counseling may be done by a counselor or nurse under the supervision of the physician. However, genetic education and counseling are time-consuming activities, and some physicians may not take the time or have the training required to provide these critical genetic testing services, and they also may not have appropriately trained staff. Genetic counseling is, in some instances, reimbursed indirectly as a hidden cost of the genetic testing process. Under the current reimbursement approach, genetic counseling is not recognized by third-party payers as a necessary component of any genetic diagnosis, testing, or screening procedure. Because of these reimbursement limitations, genetic testing and counseling are often accessible only to the middle class and wealthy—those with enough discretionary income to pay for genetics services out-of-pocket.

WHO PAYS FOR GENETIC TESTING AND COUNSELING?

Although only limited data have been available on who now pays for genetic testing and genetic counseling, third-party reimbursement for genetics services has been relatively rare. Problems of underinsured and uninsured families, and financial support for genetics services, were ranked as among the top priority issues in their respective states by state genetics services coordinators who were asked about the most important issues in genetics services facing patients and families in a 1991 Council of Regional Networks for Genetic Services survey (CORN, 1991).

Many genetics services have difficulty meeting traditional standards for reimbursement by third-party payers. Until their value has been established scientifically, new genetics services are excluded as "investigational" (see below). Yet even when a service is no longer investigational, insurers may refuse reimbursement on the grounds that it is not "medically necessary" for the diagnosis or treatment of an illness. Genetic testing and screening services generally differ from diagnostic medical testing that occurs after a patient develops symptoms. Because genetic testing is often performed on *asymptomatic* people with a family history of the disorder, many patients report that their claims for insurance reimbursement are denied (OTA, 1992b).

Geneticists, in contrast, may feel that such tests are necessary based not only on the patient's family history, but also on (1) membership in a population subgroup (by race or ethnicity) that is at a higher risk than the general population for developing a particular disorder themselves or in their offspring; (2) increased risk associated with pregnancies in women of advanced age (usually age 35 and over); and (3) screening of pregnancies for increased risk of neural tube defects, regardless of the mother's age, in order to determine whether increased risk warrants offering further prenatal genetic testing. In the future, population-wide genetic screening may be warranted, and that will require the development of appropriate reimbursement policy as well. Genetic screening may thus follow the path of certain other screening and preventive services such as mammography or immunization, which are increasingly becoming part of health insurance plans; however, counseling raises another dimension for reimbursement of genetic testing services that differs from these other screening and preventive health services.

Newborn screening is another type of genetic testing for which insurance reimbursement has been limited. In the past, most states paid directly for newborn screening tests, but now more than half the states bill the birth hospital (or more rarely the birth physician or even the parents) for the cost of newborn screening (CORN, 1992). They leave the hospital (or doctor) to collect from whatever third-party coverage the parents may have. Insurance companies, however, have resisted paying for such screening in many states, so the hospitals must somehow absorb the expense (S. Panney, Maryland Department of Health and Mental Hygiene, personal communication, 1993).

There are a few sources of noninsurance funding for genetics services that will reimburse out-of-pocket costs for persons without health insurance or whose insurer will not reimburse for genetic testing and counseling. Some academic laboratories have special research funding, some programs have state grants-in-aid (including funding from the Maternal and Child Health block grant funds to the states), some programs have limited private foundation funding, and some programs receive financial assistance available from genetic support groups. Such alternative sources of funding are not consistently available.

However, much of the complex genetic linkage analysis today is performed in academic research laboratories, and some of these laboratories bill patients for such services. Even if the proband has insurance that would cover individual genetic testing and linkage analysis, his or her insurance company may not pay for genetic testing and linkage analysis for the whole family. Extended family members are likely to have different insurance coverage that may or may not cover such procedures, and if family members are unable or unwilling to pay the costs of their own genetic testing and linkage analysis, the procedures will not produce complete and useful results. Thus, the structure of the insurance system in the United States imposes an additional impediment to genetic testing that requires linkage analysis; patients must often pay out-of-pocket or not have access to such testing.

Another barrier to coverage is the fact that most testing now performed by academic laboratories has not been approved and is therefore "investigational" under the definitions of the Food and Drug Administration. "Investigational" or "experimental" services are almost never reimbursed by third-party payers. However, most of these laboratories have not applied for or received certification under the requirements of the Clinical Laboratory Improvements Amendments of 1988. Requiring these laboratories to comply with existing federal laws (see Chapter 3) will remove some of the genetic testing and counseling these laborato-

ries currently provide as patient care from the investigational category. Thus, one additional barrier to insurance reimbursement would be reduced.

Recently, some laboratories began receiving insurance reimbursement, particularly those doing genetic testing for cancer. In addition, some patients have successfully challenged their insurer's initial refusal of payment. In a survey reported by the congressional Office of Technology Assessment (OTA, 1992b), about 40 percent of the patients were able to get their genetic test reimbursed after sending a letter from the testing laboratory to their insurer. Some patients report successfully obtaining third-party reimbursement for cystic fibrosis (CF) carrier screening, particularly during pregnancy (Bernhardt and Eierman, 1992). However, as discussed in Chapters 2 and 8, this may not be the ideal time for CF carrier testing.

PRIVATE SOURCES OF PAYMENT FOR GENETICS SERVICES

The majority of health insurance for the under-65 population in the United States is private health insurance, generally provided through employers (Fields and Shapiro, 1993).[3] In the United States, private commercial health insurance is usually a private business enterprise, run on basic business principles of responsibility to shareholders to maintain profitability (Pokorsky, 1989). Ensuring profitability for private health insurance means providing insurance to as many people as possible, while containing outlays through a variety of methods, including limits on coverage, copayments, and deductibles. Such insurance is generally provided through indemnity plans that do not cover all services.

Many health maintenance organizations (HMOs) are not for profit, but they cannot continue to operate if their coverage decisions, "open-enrollment" policies, and other practices combine to produce a continuing deficit. In this sense, even the not-for-profit insurers and managed care providers are concerned with controlling losses to their plans through coverage determinations and policies. If state insurance regulation permits, HMOs and other managed care practices may impose limits on open-enrollment periods (e.g., just a few weeks a year when they accept anyone who applies for membership) and limits on outside referrals for specialty care. The latter may impact on genetics services, which—for the most part—are outside the usual specialty services found in managed care plans. Although genetic education and counseling are essential components of any genetic testing *services* (see Chapters 1, 4, and 6), genetic counseling and education are not likely to be explicitly reimbursed without changes in reimbursement policies.

Self-Insurance by Employers

An increasing number of U.S. employers have moved to self-insurance in recent years, because it gives them more control over benefit systems and health care costs, as well as tax advantages. Federal legislation (the Employee Retirement Income Security Act, or ERISA) exempts employers from state benefits regulations. Consequently, employers may impose disease-specific dollar limits on particular diseases or conditions (see discussion of *H & H Music Company* case in Chapter 8), and are not required to meet specified state minimum benefit packages or to participate in high-risk insurance pools (for persons unable to get insurance otherwise). This complex subject is covered in a recent Institute of Medicine study, *Employment and Health Benefits* (Fields and Shapiro, 1993). It is estimated that from 50 to 60 percent of persons covered by employer-based health insurance plans participate in plans for which the company is self-insured (EBRI, 1993).

Above a certain dollar limit, the increased risk assumed by the employer for employee health expenses is then often "reinsured" against major losses through traditional insurance companies (so-called stop-loss insurance). Many businesses also contract with traditional health insurance companies to administer their health insurance plans.

Key Health Insurance Policy Barriers to Reimbursement for Genetics Services

Group health insurance coverage of genetic testing and counseling is highly variable. Most group health insurance plans—and for that matter, Medicare—limit coverage to services determined to be "medically necessary" for the treatment of a diagnosed illness or injury; they do not cover screening tests in the absence of symptoms, and thus exclude most preventive services and immunizations, in addition to much of genetic testing, education, and counseling. Where reimbursed, genetic tests may be subject to insurance company requirements for prior approval of procedures. Prenatal genetics services are more widely covered by third parties than other genetics services; many group health insurance plans and health maintenance organizations include coverage for prenatal diagnosis if recommended by the attending physician. Where coverage exists for prenatal diagnosis, however, it rarely includes full reimbursement for the time required for education and genetic counseling before and after genetic testing, and in some instances genetic education and counseling are not covered at all. Some select group plans include more liberal coverage of genetic testing.

Survey of Attitudes of Health Insurers About the Use of Genetic Information

The Office of Technology Assessment (OTA) surveyed commercial insurers, Blue Cross and Blue Shield (BC/BS) plans, and health maintenance organizations that offer individual or medically underwritten group policies (OTA, 1992b). A majority of insurers believe that the wide availability of genetic testing would have a negative financial impact on their companies unless they had access to the

results for purposes of medical underwriting.[4] None of the responding companies reported that they had done any economic analysis of the costs and benefits of carrier testing or genetic tests as part of applicant screening, although one commercial company had done an analysis of prenatal coverage. Similarly, none of the companies reported any economic analysis of providing carrier screening or genetic counseling within their benefit package. However, the survey did confirm concerns about policies and practices of insurers regarding genetic testing for CF. "On balance, however, it appears that, for now, if no medical indication for the test exists, a third-party payor generally will not pay for the (CF screening) assay" (OTA, 1992a, p. 178) (see Table 7-1).

The Impact of CPT Codes on Reimbursement

CPT-4 (current procedural terminology) codes (standardized categories used for reimbursement of health services) do not exist for many genetic tests, since the technology is developing so rapidly. In the absence of CPT-4 codes, insurance reimbursement is not possible without special review by the insurer. Some genetic testing centers are using CPT-4 codes intended for biochemical precursors to seek reimbursement from insurers. As genetic testing becomes more widespread, the lack of CPT-4 codes for genetic testing and genetic counseling will be a major impediment to insurance reimbursement even for those people who have insurance coverage for genetic diagnosis (OTA, 1992c). A committee of the American Medical Association (AMA) establishes CPT codes, including the addition of new codes. Now that the new American College of Medical Genetics (ACMG) has been recognized by the American Board of Medical Specialties (ABMS) of the AMA, the ACMG may be able to influence the AMA committee responsible for CPT-4 codes to develop appropriate codes for genetic tests.

PUBLIC SOURCES OF PAYMENT FOR GENETICS SERVICES

In some instances, public financing for genetics services occurs through Medicaid, Medicare, or state genetics services programs.

Medicare

Medicare is primarily a program to reimburse medical expenses considered "medically necessary" for people over age 65 and certain categories of disabled persons. Medicare coverage decisions and reimbursement policies related to genetic testing now affect primarily the population of persons with disabilities, some of whom would find genetics services relevant and useful. In the future, Medicare may have a broader impact, as genetic tests are developed for more disorders common to older Americans, including complex common disorders such as heart disease, cancers, diabetes mellitus, and certain mental health disorders.

TABLE 7-1 Reimbursement for Cystic Fibrosis Carrier Tests and Genetic Counseling

Question: Do your standard individual policies and medically underwritten policies provide coverage for:

Respondent	At Patient Request	Medically Indicated Only	Not Covered	No Response[a]
Individual Policies				
Carrier tests for CF?				
Commercials	0 (0%)	12 (41%)	12 (41%)	5 (17%)
HMOs	2 (18%)	7 (64%)	0 (0%)	2 (18%)
BC/BS plans[b]	2 (8%)	16 (64%)	7 (28%)	0 (0%)
Prenatal tests for CF?				
Commercials	0 (0%)	12 (41%)	14 (48%)	3 (10%)
HMOs	1 (9%)	7 (64%)	1 (9%)	2 (18%)
BC/BS plans	3 (12%)	19 (76%)	3 (12%)	0 (0%)
Genetic counseling?				
Commercials	2 (7%)	6 (21%)	18 (62%)	3 (10%)
HMOs	1 (9%)	6 (55%)	1 (9%)	3 (27%)
BC/BS plans	1 (4%)	9 (36%)	13 (52%)	2 (8%)
Medically Underwritten Policies				
Carrier tests for CF?				
Commercials	0 (0%)	24 (65%)	10 (27%)	3 (8%)
HMOs	1 (5%)	13 (65%)	2 (10%)	4 (20%)
BC/BS plans	2 (10%)	11 (52%)	8 (38%)	0 (0%)
Prenatal tests for CF?				
Commercials	1 (3%)	23 (62%)	10 (27%)	3 (8%)
HMOs	2 (10%)	14 (70%)	0 (0%)	4 (20%)
BC/BS plans	3 (14%)	14 (67%)	4 (19%)	0 (0%)
Genetic counseling?				
Commercials	2 (5%)	16 (43%)	17 (46%)	2 (5%)
HMOs	2 (10%)	12 (60%)	1 (5%)	5 (25%)
BC/BS plans	1 (5%)	7 (33%)	12 (57%)	1 (5%)

[a]Percentages may not add to 100 due to rounding.
[b]OTA also inquired about reimbursement practices for BC/BS open enrollment nongroup policies and reports these data elsewhere.

SOURCE: Office of Technology Assessment, 1992a, p. 181.

One consequence of the Deficit Reduction Act of 1984 was a change in how Medicare pays for clinical laboratory tests and services furnished to outpatients and nonpatients by hospitals, and also to patients by independent laboratories and physician offices (e.g., for certain CPT-4 codes covering laboratory processes involved in conducting and reporting certain genetic tests). Medicare fee schedules

were substantially reduced, and this reduction has subsequently been adopted by many state Medicaid programs. The low rates have reduced the number of providers who will perform these tests if Medicaid-Medicare reimbursement is the only available payment (Arkansas Medicare carrier, unpublished letter, October 1, 1991). The provisions of this 1984 legislation continues to affect reimbursement for all clinical laboratory services, including genetic tests.

Medicaid

Medicaid is a joint federal-state program to reimburse health care expenses for qualified low-income individuals and families. Preliminary data indicate variable coverage of genetic testing and counseling by state Medicaid programs (OTA, 1992a).

OTA surveyed state Medicaid directors about their coverage and reimbursement levels for selected genetics services: amniocentesis, ultrasound, chorionic villus sampling (CVS), maternal serum alpha-fetoprotein (MSAFP) screening tests, DNA analysis, chromosomal analysis, and genetic counseling. Of the 46 states whose data are included in the OTA (1992a, p. 183) report,

- 44 state Medicaid programs cover MSAFP, with average reimbursement of $21.76 (and 1 requires special review);
- 45 state Medicaid programs cover amniocentesis, with average reimbursement of $59.32;
- 44 state Medicaid programs cover fetal ultrasound, with average reimbursement of $83.13 (2 require special review of "individual considerations" to decide on coverage);
- 31 state Medicaid programs cover CVS; 10 do not cover CVS (4 require special review and 1 did not know if CVS was covered); average CVS reimbursement was $145.90;
- 41 state Medicaid programs cover chromosomal analysis from amniotic fluid or chorionic villus (1 does not cover it and 4 require special review); average reimbursement is $235.68; and
- 26 state Medicaid programs cover DNA analysis; 6 do not cover it (8 did not know if DNA analysis was covered; 6 require special review; and "family DNA testing" is covered in New York); average reported reimbursement is $33.39.

State Medicaid programs varied in whether they provided coverage of genetic counseling. As is common for many counseling services in a medical setting, genetic counseling might be covered if it were included in a general office visit code (either provided by the physician or provided by other professionals such as genetic counselors under the supervision of a physician). In 11 states, Medicaid coverage for genetic counseling is reported as part of an office visit or consultation; 19 states did not cover genetic counseling; 3 states did not know if genetic counseling was covered; and 2 states required special review. The average reimbursement of $68.87 reported for genetic counseling actually reflected the range of reimbursements for different levels of physician office visits, rather than for genetic counseling per se (OTA, 1992a, p. 182).

Medicaid reimbursement is available for some genetic laboratory testing services, but the Medicare reimbursement practice of setting "maximum allowable charges" for particular tests and then reimbursing a percentage (generally 80 percent of maximum allowable charges) has had a negative impact on Medicaid practices (Arkansas Medicare carrier, unpublished letter, October 1, 1991). Although good data are not available, estimates indicate that Medicaid pays less than half of the actual charges for some of the genetic tests for which it reimburses. It is frequently difficult to find providers of genetic testing services who will accept patients for whom Medicaid is the only reimbursement available. In addition, not all genetics centers accept state Medicaid reimbursement. "Those genetic service providers that accept Medicaid patients must subsidize the costs" (OTA, 1992a, p. 184).

CHAMPUS

The federal government also finances some genetic testing and screening services through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), the primary health insurer for military dependents and retirees. CHAMPUS has adopted basic concepts similar to those of private insurers and state Medicaid programs for genetic testing and related services. It covers genetic testing for couples identified as "high risk," for example, due to prior births of affected children, but specifically excludes routine screening of low-risk pregnancies (Charo, 1992).

State Genetics Services Programs

State genetics services programs vary widely (CORN, 1991). Some states provide limited genetics services directly; most states coordinate at least some genetics services, particularly with Medicaid, Medicare (which sets reimbursement rates used by state Medicaid programs), and other possible funding sources (such as programs for persons with mental retardation or developmental disabilities, or for children with special needs) to help secure funding for people who cannot afford needed genetics services. All of the 41 states responding to a recent CORN survey reported some level of coordinated state genetics services, and 60 percent of these have a full-time state genetics services coordinator (CORN, 1991). Coordinators are located in a wide variety of state agencies, although nearly 80 percent are in the state health department, usually in the maternal and child health (MCH) program.

Of the 41 state programs that responded to the CORN survey, 84 percent

were initially established with federal funding under the Genetic Diseases Act of 1976.[5] Most (77 percent) still receive some support for genetics services from the state through federal Maternal and Child Health block grant funds (Public Law 997-35), to which funding from the Genetic Diseases Act was transferred in 1981. However, MCH block grants generally represented less than 25 percent of total state funding. Nearly half the programs reported a decrease in block grant funding when inflation is taken into account (CORN, 1991). Many state genetics services programs historically paid for newborn screening, but the majority now charge birth hospitals, attending physicians, or parents for newborn screening.

A few state programs have more extensive authorization and funding that permits them to provide or pay for genetic testing or genetic counseling. State genetics services programs also vary in their policies toward the use of genetic testing information for abortion counseling (Clayton, 1993). Several states specifically attempt to limit use of available state genetics services when the goal is selective abortion of affected fetuses. Minnesota and Missouri provide extensive genetic testing services, but almost no funding for abortion services; Tennessee's extensive prenatal diagnosis program is limited to conditions leading to treatment in the mother or the baby, but its legislation states that "use of this program to abort unborn children is against the public policy of the State of Tennessee" (Tennessee Code Annotated, 1991, §§ 68-5-501-505).

Thus, the committee sees (1) wide variation in policy, practice, and funding within state programs; (2) differences in reimbursement policies and practices among third-party payers concerning reimbursement for genetic testing and counseling services; and (3) regulatory, administrative, and funding barriers to coverage and reimbursement of appropriate genetics services.

Federal Support for Genetics Services Programs

The federal government still maintains a small amount of direct project grant funding for Special Projects of Regional and National Significance (SPRANS) through the Genetic Services Branch, Maternal and Child Health Services Bureau, Health Resources and Services Administration, in the Department of Health and Human Services. These special project grants are available on a competitive basis for genetics projects of special regional or national significance, but are not intended to replace the ongoing state funding that was transferred to block grants in 1981. These grants have funded special projects around the nation as well as many activities of the Council of Regional Networks for Genetic Services (CORN), including its genetics services data collection, newborn screening, and laboratory quality assurance activities. Special project funds have also supported activities of the Alliance of Genetic Support Groups. Federal funding has reached slightly more than $9 million for fiscal year 1993 for SPRANS grants, essentially the same level of funding received for 1992.

RECOMMENDATIONS

The committee believes that education and counseling are essential components of any genetic testing (see Chapter 4). In order to develop appropriate reimbursement for genetic testing and counseling services, the committee recommends that greater efforts be made for joint undertakings among private and public health plans and geneticists to develop guidelines for the appropriate reimbursement of genetics services. Such guidelines should address the issue of how each new genetic test should be assessed for its sensitivity and specificity in light of the availability of effective treatment, the consequences of the test, the evaluation of pilot study results, and when new tests are appropriate for use in routine clinical practice.

The insurance concept of what is reimbursable (so-called medically necessary) should be defined to include appropriate genetic testing and related education and counseling, and these genetics services be reimbursed under health insurance plans. Medical necessity can often be established by a family history of the disorder. In pregnancy, medical necessity should be considered established for cytogenetic testing in pregnancies in women of advanced maternal age or those considered at high risk based on other methods of assessing risk. The committee also recommends that newborn screening and appropriate MSAFP screening in pregnant women of any age be considered within the insurance definition of what is medically appropriate, and be reimbursed under health insurance plans.

To facilitate such coverage and reimbursement for genetic testing, education, and counseling, the committee recommends the establishment and updating of appropriate and specific CPT-4 diagnostic codes for these genetic testing and counseling services. Now that the ACMG has become part of the ABMS of the AMA, the ACMG should take the lead in working with the AMA committee responsible for CPT-4 codes.

Finally, the committee recommends that health insurance reform proposals be evaluated to determine whether they adequately protect genetic information and persons with genetic disorders from discrimination and other potential social, legal, and ethical harms related to health insurance and the use of genetic information (see Chapters 7 and 8).

NOTES

1. The Committee on Assessing Genetic Risks had the benefit of the advice of Marilyn Field, Study Director of the Institute of Medicine (IOM) Committee on Employer Based Benefit Plans in preparing its analysis of issues of health insurance and its impact on access to genetic testing and counseling services.

2. The full report of the ELSI Task Force on Insurance and Genetic Testing covers many of these issues in more detail and was released in May 1993 (ELSI Insurance Task Force, 1993). Committee staff followed the work of the ELSI Task Force so that the IOM committee had the benefit of this work in its own deliberations.

3. For additional information, see the recent IOM report *Employment and Health Benefits: A Connection at Risk* (Fields and Shapiro, 1993).

4. Medical underwriting is the evaluation of a person's insurability, usually assessed through a combination of answers to a written questionnaire and physical examination to identify certain conditions determined by medical underwriters (and underwriting manuals) to reduce life expectancy or increase medical care costs beyond actuarial norms. Standards for medical underwriting vary substantially by insurance company, and underwriting decisions are considered crucial business decisions by insurers, and are thus considered "trade secrets" not subject to public disclosure.

5. The National Sickle Cell Anemia, Cooley Anemia, Tay-Sachs, and Genetic Diseases Act of 1976 (Public Law 94-278) consolidated separate 1972 legislation for sickle cell anemia (Public Law 92-294) and Cooley anemia (Public Law 92-414) and added other genetic conditions into the provisions of the law. It required the development of information and education materials "to persons providing health care, to teachers and students, and to the public in general in order to rapidly make available the latest advances in the testing, diagnosis, counseling and treatment of individuals respecting genetic disease." It also required that federally assisted programs for the disorders included were to be entirely voluntary. Although this legislation was repealed in 1981, with the passage of the Maternal and Child Health Services Block Grant Act (Public Law 97-35), the requirement that programs supported with block grant funds be entirely voluntary was never repealed.

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8 Social, Legal, and Ethical Implications of Genetic Testing

Each new genetic test that is developed raises serious issues for medicine, public health, and social policy regarding the circumstances under which the test should be used, how the test is implemented, and what uses are made of its results. Should people be allowed to choose or refuse the test, or should it be mandatory, as newborn screening is in some states? Should people be able to control access to the results of their tests? If test results are released to third parties such as employers or insurers, what protections should be in place to ensure that people are not treated unfairly because of their genotype?

The answers to these questions depend in part on the significance given to four important ethical and legal principles: autonomy, confidentiality, privacy, and equity. A review of the meaning of those concepts and how they are currently protected by the law provides a starting point for the development of recommendations on the degree of control people should have in deciding whether to undergo genetic testing and what uses should be made of the results. The task is a pressing one. In a 1992 national probability survey of the public, sponsored by the March of Dimes, 38 percent of respondents said that new types of genetic testing should be stopped altogether until the privacy issues are settled.[1]

This chapter reviews some of the conflicts that will arise in the research and clinical settings, and suggests general principles that should be the starting point for policy analyses in this evolving field.

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[1] Since many of the references in this chapter are legal citations, its references appear in legal style as numbered end notes.

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Printed in the USA.

A Survey of Reimbursement for Cystic Fibrosis Carrier Testing

Barbara A. Bernhardt[1,2]

To assess the current status of reimbursement for cystic fibrosis (CF) carrier testing, we surveyed individuals tested in the Mid-Atlantic region. Results show that CF testing was covered by insurance in part or in full for greater than 50% of respondents. The test was nearly always covered when performed during pregnancy because of a positive family history, but it was also covered for more than 50% of pregnant respondents with a negative family history. There were no significant differences in coverage by type of insurance. Many respondents needed to supply additional information about the testing to their insurance company before a coverage decision could be made. Before population-based CF screening programs are initiated, more data are needed on insurance reimbursement for testing, especially when performed pre-conceptually.

KEY WORDS: cystic fibrosis; genetic services; genetic screening; carrier testing; reimbursement.

INTRODUCTION

Recent technological advances have made it possible to offer cystic fibrosis (CF) carrier screening to large segments of the population. However, the American Society of Human Genetics stated in 1990 and reiterated in 1992 that routine CF carrier screening is not yet recommended for individuals or couples who do not have a family history of CF (American Society of Human Genetics, 1990, 1992), a stand also supported by the

[1]Genetics and Public Policy Studies, Johns Hopkins School of Medicine, Baltimore, Maryland.
[2]Correspondence should be directed to Barbara A. Bernhardt, Genetics and Public Policy Studies, Johns Hopkins Medical Institutions, 550 North Broadway, Suite 301, Baltimore, Maryland 21205.

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National Institutes of Health (NIH Workshop on Population Screening for the Cystic Fibrosis Gene, 1990). Despite these recommendations, some groups believe that the current test should now be offered to individuals without a positive family history as a part of general obstetric or prenatal diagnostic services (Brock, 1990; Schulman *et al.*, 1990).

In considering guidelines for CF carrier screening, the NIH Workshop urged that ". . . when population-based screening becomes widespread . . . there should be equal access to testing." Ensuring equal access to testing will require government subsidy of testing or adequate insurance reimbursement for the test (Bernhardt, 1991). Because subsidized programs for voluntary genetic carrier screening are unlikely to be established, consumers will rely on their medical insurance for coverage of CF carrier screening. Recent surveys by the Office of Technology Assessment have shown that DNA analysis is covered by 57% of States' Medicaid programs, with an average reimbursement of $33.39, and that no commercial insurers will cover CF carrier testing for screening purposes only (U.S. Congress, Office of Technology Assessment, 1992a).

This survey was undertaken to assess the current reimbursement status of CF DNA carrier testing. Clients, rather than insurers, were surveyed in order to obtain data on the actual reimbursement experience of individuals tested, instead of data on how insurers report they would or would not cover the cost of testing. To obtain a sample of individuals who were tested for a variety of indications, clients were surveyed through genetic counselors throughout the Mid-Atlantic region. Some participating genetics centers had set up policies regarding CF carrier screening, such as offering screening to women being seen for consideration of prenatal diagnosis for another indication, or to offer screening to consanguineous couples referred for genetic counseling. No center was offering routine preconceptual screening to individuals without a family history of CF.

METHODS

A two page client self-administered questionnaire was developed to gather data on date of testing, number of family members tested, pregnancy status at the time of testing, indications for testing, type of insurance, cost of testing, insurance coverage of the test, and reasons for possible denial of coverage. To keep the questionnaire as brief as possible, no demographic data were collected.

One hundred and two genetic counselors from 35 genetics centers in the Mid-Atlantic region were sent a letter explaining the study, a supply of the questionnaire, a sample of a cover letter to accompany the questionnaire, and a supply of return envelopes. They were asked to mail the questionnaire, along with a modification of the cover letter printed on their own letterhead, to their clients (representing a single individual tested, a couple, or a family) who had CF testing performed in 1990 or 1991 and who were billed, or whose insurance was billed, for the test. Clients with Medicaid coverage were not surveyed, but counselors were asked if they had knowledge of coverage for cystic fibrosis testing by their state's Medicaid program. To determine survey response rate, counselors were asked to report the number of questionnaires mailed out. Clients answered the questionnaire anonymously, but were asked to supply the name of the center where they were seen for genetic counseling. Counselors were informed that they would receive a summary of the reimbursement experience of their clients at the conclusion of the study.

RESULTS

Counselors from 18 centers mailed questionnaires to 216 clients. The number of questionnaires sent from any center ranged from 1 to 60. One hundred nine questionnaires were completed and returned for a response rate of 50%. Response rates by center varied from 0% to 100%. No attempts were made to follow up those who did not respond to the initial mailing. Four of the returned questionnaires involved testing performed after the study period and were excluded from further analysis. The results are based on the analysis of 105 completed questionnaires.

Seventy-four percent of respondents had CF testing done during pregnancy and 54% of the total group had a positive family history. Sixty-nine of the respondents indicated the exact charge for each CF DNA test. The reported mean charge per test was $189 with a range from $110 to $272. Fifty-six percent of respondents had carrier testing only, 15% had both carrier and fetal testing, and 29% had fetal testing only. This latter group were all tested through one center where fetal CF screening is offered to Caucasian patients presenting for prenatal diagnosis for any indication.

The percentage of respondents reporting that the cost of testing was covered in full, in part, or not at all is shown in Fig. 1. For those reporting that the test was covered in part by their insurance company, most indicated that they were responsible for only a small portion of the total charge (usually 20%) that was not routinely covered by insurance. Of the 32 respondents reporting that the testing was not covered, the reasons cited for non-coverage were: "DNA testing is not a service covered by my insurance policy" (59%), "DNA testing is considered experimental" (3%), "DNA testing was considered not medically indicated" (28%), and "deductible was

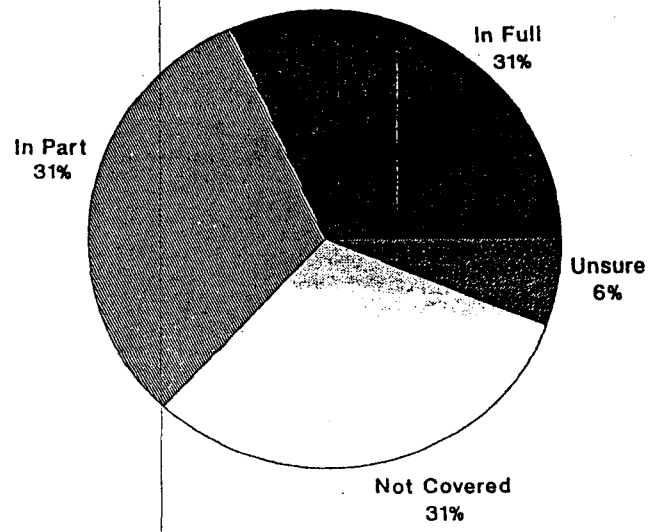

Fig. 1. Insurance coverage of test.

not met" (9%). There were no significant differences in coverage between tests performed in 1990 and those done in 1991.

Coverage of the test by type of insurance is shown in Table I. The six respondents who were unsure of coverage of the test were excluded from this analysis and those whose tests were covered in part or in full were combined into one category. Testing was covered greater than 50% of the time by all types of insurance. By chi-square testing, there were no significant differences in coverage by type of insurance. Twenty-four percent of respondents reported needing to supply information to their insurance company before a final decision about coverage was made. The information requested by the insurance company related to indication for testing, confirmation of family history status, or further description of the test performed. Of this group, 76% eventually had the cost of their testing covered in part or in full by their insurance company.

Data on coverage of the test by family history and pregnancy status are shown in Table II. The six respondents who were unsure of coverage of the test were excluded from this analysis and those whose tests were covered in part or in full were combined into one category. By chi-square testing, there was a significant association between pregnancy status/family history and insurance coverage of the test. The test was covered almost

Table I. Coverage of Test by Type of Insurance[a]

Type of insurance	N	Coverage of test	
		In full/in part (%)	Not covered (%)
Blue Cross/Blue Shield	27	70	30
HMO	22	59	41
Other commercial	39	69	31
Employer	7	71	29
CHAMPUS	3	67	33
Total	98		

[a] $\chi^2_{4df} = .889$; $p = .926$.

Table II. Coverage of Test by Family History (FH) and Pregnancy Status[a]

Pregnancy/FH status	N	Coverage of test	
		In full/in part (%)	Not covered (%)
Pregnant, positive FH	28	93	7
Pregnant, negative FH	46	59	41
Not pregnant, positive FH	23	52	47
Not pregnant, negative FH	1	0	100
Total	98		

[a] $\chi^2_{3df} = 16.59$; $p < .001$.

uniformly for pregnant respondents who had a positive family history. Fifty-nine percent of pregnant respondents without a family history of cystic fibrosis had their test covered in part or in full while a somewhat smaller percentage (52%) of those not pregnant, but having a positive family history, had the test covered.

None of the 28 counselors responding to the survey indicated that they had any knowledge of Medicaid coverage for CF carrier testing.

DISCUSSION

Pilot projects are currently underway to address some of the research questions, such as test sensitivity and effectiveness of educational materials, relating to population-based cystic fibrosis carrier screening. These projects will also identify the most appropriate target population for screening, as well as the most appropriate clinical settings for screening.

Both the NIH statement on CF carrier screening and a recent survey of genetic counselors (U.S. Congress, Office of Technology Assessment, 1992b) have emphasized the importance of preconceptional screening so as to maximize the number of reproductive options open to at-risk couples.

However, these data on test coverage for non-pregnant respondents indicate that the test was covered only 52% of the time, even though all but one of these respondents reported a positive family history of cystic fibrosis. More data on test coverage when performed on non-pregnant individuals with a negative family history would resolve the issue of anticipated access to preconceptual testing. However, given that a recent OTA survey of insurers indicated that no commercial insurance company would reimburse for CF carrier test for screening purposes only (U.S. Congress, Office of Technology Assessment, 1992c), it is likely that actual survey data would show reimbursement for preconceptual testing to be poor.

Because many people are traditionally referred for genetic services through their obstetrical providers, it is more likely that screening programs will be aimed at pregnant women and their partners (U.S. Congress, Office of Technology Assessment, 1992a). The cost of the test and the extent to which insurance companies cover the cost of screening will impact greatly on test utilization. At present, the majority of insurers report that carrier tests for cystic fibrosis are covered if "medically indicated" (U.S. Congress, Office of Technology Assessment, 1992c). The definition of medical indications for testing will therefore influence how widespread testing becomes. If, based on recommendations of expert panels and professional societies, it is deemed medically indicated to offer CF carrier screening to pregnant women, insurers may gradually cover the cost of testing. Insurers, in fact, appear to be inclined toward covering the cost of CF screening during pregnancy as evidenced by the fact that nearly 60% of pregnant women with a negative family history responding to this survey indicated that testing was covered by their insurer. Nearly 1/4 of respondents to this survey needed to supply their insurer with additional information before a determination about coverage could be made. This may indicate that guidelines for test coverage are not yet strictly spelled out, probably due to insurers' lack of experience with claims submitted for coverage of CF DNA testing.

Another obstacle to adequate insurance reimbursement for CF carrier testing may be the lack of a descriptive procedure (CPT) code for CF DNA testing which is recognized by third party payers. Lack of such a code may result in non-coverage of testing, or in reimbursement at a rate much lower than the amount charged. New CPT codes for molecular genetics procedures are being developed and will be available for use soon. Although using these codes for billing might improve reimbursement, insurers will still need to determine if the procedures are to be covered and under which circumstances, and, if covered, the payment schedule.

Because of small sample size and low response rate, the results of this preliminary study need to be interpreted cautiously. A number of factors may have contributed to small sample size. First, genetic counselors

were asked to identify clients who had CF carrier testing performed and to mail out questionnaires. By anecdotal reports, it appears that such retrospective identification of survey subjects was problematic and that time was often unavailable to mail out questionnaires and the cover letter. Therefore, some clients who were tested did not receive questionnaires. In addition, only 50% of subjects receiving the questionnaire completed it. Completion of the questionnaire involved retrieving some cost and insurance reimbursement information, which might be partially responsible for the low response rate. If such a reimbursement study were carried out in the future, prospective identification by genetic counselors of clients who could complete a survey soon after testing might increase both sample size and response rate.

It is also possible that some respondents were tested only because they knew the test would be covered by their insurance, thereby increasing the percentage of individuals indicating coverage of the test. Many people offered testing may have declined it because their insurance company would not cover it.

Despite these limitations, because the responses to this survey are derived from clients tested through many genetics centers and for a variety of indications, it is felt that they are likely to reflect the actual current status of reimbursement for cystic fibrosis carrier testing.

CONCLUSIONS AND RECOMMENDATIONS

The results of this study indicate that CF carrier testing is often covered by insurance, especially when performed during a pregnancy. There is not, however, uniform coverage of the test, not even when performed because a positive family history, which is generally recognized as a legitimate medical indication for doing the test.

Genetic counselors should make clients aware that CF carrier testing might not be covered by insurance, especially if performed preconceptually. Counselors should urge clients to appeal denials of coverage, particularly when testing is medically indicated.

More data are needed on reimbursement for CF DNA testing, especially the experience of non-pregnant individuals. As testing becomes more widespread for consumers without a positive family history, insurers will need to be educated about appropriate medical indications for testing and insurance coverage of testing will need to be carefully and continuously monitored.

ACKNOWLEDGMENTS

The author thanks Ellen Tambor for assisting with data analysis and Lindsay Eierman for her valuable suggestions. This project was supported in part by Grant No. MCJ-421008-01 from the Maternal and Child Health Program, Human Resources and Services Administration, Department of Health and Human Services.

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Scientific Aspects of Early Eugenics

Mark S. Lubinsky[1,2]

The eugenics movement supported applications of scientific breeding principles to humans, ultimately to encourage a better society, but actually with often disastrous social consequences. Although mostly viewed as quackery today, legitimate scientific considerations of fact and theory had an important role in determining the course of eugenics. A school of eugenics arose formally from attempts to apply Darwinian principles to humans in the context of biometry, a school that used statistical approaches to biology. Biometry emphasized blending inheritance and continuous traits, in marked contrast to the particulate inheritance of unit traits in Mendelism. Genetics was therefore a scientific challenge to eugenics, which was rooted in biometry. A Mendelian eugenics arose in the United States primarily under the influence of Charles Davenport. This paper reviews some of the technical issues involved in the development of this new paradigm, as well as Davenport's role as a scientist in this process.

KEY WORDS: biometry; Charles Davenport; eugenics; Mendelism.

INTRODUCTION

Certain convictions about what genetic counseling *does not* involve have helped shape the profession. These negative influences are largely reactions against uses of genetics "for the greater good of society." The heart of such now rejected approaches was eugenics, supposedly scientific extensions of breeding principles to humanity. The linkages of genetics with issues of race, class, and so on that followed led to often disastrous consequences in our century.

[1]Department of Pediatrics, Medical College of Wisconsin, Milwaukee, Wisconsin.
[2]Correspondence should be directed to Mark Lubinsky, Division of Genetics, Childrens Hospital of Wisconsin, Box 1997, Milwaukee, Wisconsin 53201.

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Chapter 4

Coverage and Reimbursement

Will health insurers pay for voluntary screening and followup counseling? And will health insurance companies authorize payment for prenatal screening or testing of newborn *children?* Answers to these questions carry significant cost implications. They also will likely affect the degree to which carrier screening for cystic fibrosis (CF) becomes commonlace, since many people will be unwilling to pay out-of-pocket the costs of the assays (1). From the perspective of the commercial laboratory that provides genetic tests to medical providers and patients, the issue of reimbursement is crucial to business—current and future.

OTA asked health insurers covering individuals and medically underwritten groups about their coverage of certain genetic tests and services. Are they covered 'at patient request," where there is no family history (i.e., screening)? Are they covered ''only if medically indicated, ' where a family history exists? Or, are they "not covered"?

REIMBURSEMENT FOR GENETIC TESTS AND SERVICES

No commercial company reimburses for CF carrier tests for screening purposes. The survey also found that carrier tests for CF—as well as for Tay-Sachs and sickle cell-are not covered for any reason by 12 of 29 commercial insurers that offer individual coverage. Twelve respondents (41 percent) cover CF carrier assays if medically indicated. With respect to prenatal tests for CF, about 41 percent (12 respondents) that write individual policies reimburse for such tests when medically indicated.

For the 37 commercial companies offering medically underwritten group policies, carrier tests for CF (and, again, for sickle cell or Tay-Sachs) are not covered by any company when done solely at patient request. CF mutation analysis is covered by 24 of 37 companies if medically indicated. Ten companies offering medically underwritten group coverage do not cover any of the carrier or prenatal tests asked about in OTA's survey. Sixty-two percent of companies (23 respondents) that offer medically underwritten group policies cover prenatal tests for CF when medically indicated (table 4-l).

Two of 25 Blue Cross and Blue Shield (BC/BS) plans offering individual coverage would reimburse CF carrier screening at patient request. Sixteen of these BC/BS plans (64 percent) cover them if they are medically indicated and seven do not cover them. Three of 25 BC/BS plans cover prenatal testing for CF at a patient's request, seven if medically indicated, and three not at all. Of 21 BC/BS plans offering coverage to medically underwritten groups, CF carrier screening is covered at patient request by only 2 companies (10 percent), if medically indicated by 11 companies (52 percent), and not at all by 8 companies (38 percent) (table 4-l). Data on coverage for CF prenatal tests by BC/BS plans that cover medically underwritten groups are also presented in table 4-1.

For the 11 health maintenance organizations (HMOS) that offer health insurance to individuals, 1 HMO (9 percent) covers CF carrier tests at patient request and 7 HMOS (64 percent) reimburse for them if medically indicated. For the 20 HMOS that offer medically underwritten group contracts, 1 HMO (5 percent) covers CF carrier tests at patient request, 13 respondents (45 percent) reimburse for them if medically indicated, and 2 (10 percent) do not cover them at all. Table 4-1 presents these results as well as how HMOS cover prenatal tests for CF.

From OTA's survey results, it is evident that carrier and prenatal tests often are not covered under individual and medically underwritten group policies unless they are medically necessary-i. e., unless a family history exists. Such policies can have a significant impact on both the rate at which CF carrier screening becomes routine and the ultimate utilization of CF mutation analysis.

OTA found that genetic counseling was not covered by 18 commercial companies offering individual coverage and 17 offering medically underwritten group coverage. Six commercial insurance companies offering individual policies and 16 that medically underwrite groups cover genetic counseling only if it is medically indicated. Two commercial companies offering each type of cover-

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Table 4-I-Reimbursement for Genetic Tests and Genetic Counseling

Question	Respondent	At patient request	Medically indicated only	Not revered	No responsea
Do your standard individual policies and medically underwritten policies provide coverage for:					
Individual policies					
Carrier tests for CF?	Commercials	0 (0%)	12 (41%)	12 (41%)	5 (18%)
	HMOS	2 (18%)	7 (64%)	0 (0%)	2 (18%)
	BC/BS plans-u*	2 (8%)	16 (64%)	7 (28%)	0 (0%)
	BC/BS plans-M	0 (0%)	11 (61%)	5 (28%)	2 (11%)
Carrier tests for Tay-Sachs?	Commercials	0 (0%)	12 (41%)	12 (41%)	5 (18%)
	HMOS	2 (18%)	7 (64%)	0 (0%)	2 (18%)
	BC/BS plans-U	2 (8%)	16 (64%)	7 (28%)	0 (0%)
	BCLBS plans-M	0 (0%)	11 (61%)	5 (28%)	2 (11%)
Carrier tests for sickle Cell trait?	Commercials	0 (0%)	12 (41%)	12 (41%)	5 (18%)
	HMOS	3 (27%)	6 (55%)	0 (0%)	2 (18%)
	BC/BS plans-U	2 (8%)	16 (64%)	7 (28%)	0 (0%)
	BC/BS plans-M	0 (0%)	11 (61%)	5 (28%)	2 (11%)
Prenatal tests for CF?	Commercials	0 (0%)	12 (41%)	14 (48%)	3 (10%)
	HMOS	1 (9%)	7 (64%)	1 (9%)	2 (18%)
	BC/BS plans-U	3 (12%)	19 (76%)	3 (12%)	0 (0%)
	BC/BS plans-M	1 (5%)	13 (73%)	2 (11%)	2 (11%)
Prenatal tests for Tay-Sachs?	Commercials	0 (0%)	11 (38%)	15 (52%)	3 (10%)
	HMOS	2 (18%)	8 (73%)	0 (0%)	1 (9%)
	BCLBS plans-U	3 (12%)	19 (76%)	3 (12%)	0 (0%)
	BC/BS plans-M	1 (5%)	13 (73%)	2 (11%)	2 (11%)
Prenatal tests for sickle cell anemia?	Commercials	0 (0%)	11 (38%)	15 (52%)	3 (10%)
	HMOS	1 (9%)	8 (73%)	0 (0%)	2 (18%)
	BC/BS plans-U	3 (12%)	19 (76%)	3 (12%)	0 (0%)
	BC/BS plans-M	1 (5%)	13 (73%)	2 (11%)	2 (11%)
Prenatal tests for Down syndrome?	Commercials	1 (4%)	10 (34%)	15 (52%)	3 (10%)
	HMOS	1 (9%)	9 (82%)	0 (0%)	1 (9%)
	BC/BS plans-U	3 (12%)	19 (76%)	3 (12%)	0 (0%)
	BC/BS plans-M	1 (5%)	13 (73%)	2 (11%)	2 (11%)
Genetic counseling?	Commercials	2 (7%)	6 (21%)	18 (62%)	3 (10%)
	HMOS	1 (9%)	6 (56%)	1 (9%)	3 (9%)
	BC/BS plans-U	1 (4%)	9 (36%)	13 (52%)	2 (8%)
	BC/BS plans-M	0 (0%)	8 (44%)	8 (44%)	2 (12%)

age (individual and medically underwritten) reimburse for genetic counseling performed at patient request (table 4-l). Similar results for BC/BS plans and HMOS are also presented in table 4-1.

COVERAGE FOR CYSTIC FIBROSIS CARRIER TESTS

In contrast to questions that inquire about what the respondent's company policy would be, respondents were also asked whether they were aware if their organization had ever actually reimbursed for CF carrier tests. Regardless of the type of respondent, CF carrier testing has been reimbursed at roughly the same frequency for all (table 4-2). For commercial insurers, 11 of the 51 respondents (22 percent) said their companies had reimbursed for such tests, and 35 respondents (69 percent) indicated their companies had not. Of the 23 HMOS that responded to the OTA survey, 7 (30 percent) had reimbursed for CF carrier testing, and 14 (61 percent) had not. Of the 29 BC/BS plans represented by the underwriter survey, 7 (24 percent) had reimbursed for CF carrier testing, and 18 (62 percent) had not. Five of the 18 (28 percent) BC/BS plans represented by a medical director survey had reimbursed for CF carrier testing, and 12 (67 percent) had not.

Table 4-I—Reimbursement for Genetic Tests and Genetic Counseling Continued

Question	Respondent	At patient request	Medically indicated only	Not covered	No response[a]
Medically underwritten groups					
Carrier tests for CF?	Commercials	0 (0%)	24 (65%)	10 (27%)	3 (8%)
	HMOS	1 (5%)	13 (65%)	2 (10%)	4 (20%)
	BC/BS plans-U	2 (10%)	11 (52%)	8 (38%)	0 (0%)
	BC/BS plans-M	0 (0%)	9 (60%)	4 (27%)	2 (13%)
Carrier tests for Tay-Sachs?	Commercials	0 (0%)	22 (59%)	11 (30%)	4 (11%)
	HMOS	1 (10%)	13 (60%)	2 (10%)	7 (20%)
	BC/BS plans-U	2 (10%)	11 (52%)	8 (38%)	0 (0%)
	BC/BS plans-M	0 (0%)	9 (60%)	4 (27%)	2 (13%)
Carrier tests for sickle cell trait?	Commercials	0 (0%)	23 (62%)	10 (27%)	4 (11%)
	HMOS	2 (10%)	12 (60%)	2 (10%)	4 (20%)
	BC/BS plans-U	2 (10%)	11 (52%)	8 (38%)	0 (0%)
	BC/BS plans-M	0 (0%)	9 (60%)	4 (27%)	2 (13%)
Prenatal tests for CF?	Commercials	1 (3%)	23 (62%)	10 (27%)	3 (8%)
	HMOS	2 (10%)	14 (70%)	0 (0%)	4 (20%)
	BC/BS plans-U	3 (14%)	14 (67%)	4 (19%)	0 (0%)
	BC/BS plans-M	1 (7%)	11 (73%)	1 (7%)	2 (13%)
Prenatal tests for Tay-Sachs?	Commercials	1 (3%)	24 (65%)	10 (27%)	2 (5%)
	HMOS	3 (15%)	14 (70%)	0 (0%)	3 (15%)
	BC/BS plans-U	3 (14%)	14 (67%)	4 (19%)	0 (0%)
	BC/BS plans-M	1 (7%)	11 (73%)	1 (7%)	2 (13%)
Prenatal tests for sickle cell anemia?	Commercials	1 (3%)	24 (65%)	10 (27%)	2 (5%)
	HMOS	2 (10%)	14 (70%)	0 (0%)	4 (20%)
	BC/BS plans-U	3 (14%)	14 (67%)	4 (19%)	0 (0%)
	BC/BS plans-M	1 (7%)	11 (73%)	1 (7%)	2 (13%)
Prenatal tests for Down syndrome?	Commercials	2 (5%)	23 (62%)	10 (27%)	2 (5%)
	HMOS	2 (10%)	15 (75%)	0 (0%)	3 (15%)
	BC/BS plans-U	3 (14%)	14 (67%)	4 (19%)	0 (0%)
	BC/BS plans-M	1 (7%)	11 (73%)	1 (7%)	2 (13%)
Genetic counseling	Commercials	2 (5%)	16 (43%)	17 (46%)	2 (5%)
	HMOS	2 (10%)	12 (60%)	1 (5%)	5 (25%)
	BC/BS plans-U	1 (5%)	7 (33%)	12 (57%)	1 (5%)
	BC/BS plans-M	0 (0%)	6 (40%)	7 (47%)	2 (13%)

a Percentages may not add to 100 due to rounding.
bBC/BS plans represents the underwriter population and BC/BS plans-M, the medical director Population.

SOURCE: Office of Technology Assessment, 1992.

ECONOMIC ANALYSIS OF GENETIC TESTS

To determine whether insurance companies have looked into the economic implications of various genetic tests, OTA asked if companies had ever conducted an economic analysis of the costs and benefits of various testing schemes. OTA found that no commercial insurer had conducted an economic analysis of the costs and benefits of carrier or other genetic tests as part of applicant screening. In addition, no commercial company had conducted an economic analysis of the costs and benefits of genetic counseling of carriers who are covered. One commercial company reported it had done an analysis of the costs and benefits of carrier tests as part of prenatal coverage, but 48 of 51 companies had not (table 4-3).

Survey respondents from HMOS had not conducted an economic analysis of the costs and benefits of carrier testing for either applicant screening or prenatal coverage, No economic analysis had been conducted by HMOS on genetic testing for applicant screening. One company conducted an economic analysis of the costs and benefits of genetic counseling of carriers who are covered.

Similar results were found for BC/BS plans. One of the 29 BC/BS plans represented by an underwriter

Table 4-2-Coverage for Cystic Fibrosis Carrier Tests

Respondent	Yes	No	No response*
Commercials	11 (22%)	35 (69%)	5 (9%)
HMOS	7 (30%)	14 (61%)	2 (9%)
BC/BS plans-U*	7 (24%)	18 (62%)	4 (14%)
BC/BS plans-M	5 (28%)	12 (67%)	1 (5%)

*Percentages may not add to 100 due to rounding.
bBC/BS plans-u represents the underwriter population and BC/BS plans-M, the medical director population.
SOURCE: Office of Technology Assessment, 1992.

survey had conducted an economic analysis of the costs and benefits of genetic counseling of carriers who are covered, and 1 had conducted an economic analysis of carrier testing as part of prenatal coverage. None of the BC/BS plans represented by the underwriter survey had conducted an economic analysis of carrier or genetic testing as a part of applicant screening.

One of the 18 BC/BS plans represented by the medical director survey had conducted an economic analysis of carrier testing as part of prenatal coverage. Otherwise, none of the medical directors at the responding BC/BS plans had conducted an economic analysis of carrier or genetic testing as part of applicant screening, or of genetic counseling of carriers who are covered.

PERSPECTIVES ON FUTURE REIMBURSEMENT FOR GENETIC TESTS

As new genetic tests come on line, will insurers alter their claims payment practices? When asked if they would alter claims payment practices in the next 5 years, nearly half of commercial insurers (23 of 51; 45 percent) considered it "very unlikely," while one quarter (12; 24 percent) found it "somewhat likely"; only two companies thought it was likely (table 4-4). When commercial insurers were asked to project ahead a decade, 23 of 51 companies responded that it would be very or somewhat likely that their company would alter claims payment practices as new genetic tests came on line; 28 companies thought it would be somewhat or very unlikely.

Underwriters from 10 BC/BS plans responded it was "somewhat likely" that claims payment practices would be altered as new genetic tests came on line, 9 thought it "somewhat unlikely' and 7 thought it was "very unlikely." More BC/BS underwriters thought it was "somewhat likely" (11 of 29) in 10 years. Six BC/BS plans represented by an underwriter survey thought it was "very likely" and seven thought it "very unlikely. "

Table 4-3-Economic Analyses of Genetic Tests and Genetic Counseling by Insurers

Question	Respondent	Yes	No	No response*
Has your company ever conducted an economic analysis of:				
Carrier testing as part of applicant screening?	*Commercials*	0 (0%)	50 (98%)	1 (2%)
	HMOs	0 (0%)	20 (87%)	3 (13%)
	BC/BS plans-U[b]	0 (0%)	28 (94%)	1 (3%)
	BC/BS plans-M	0 (0%)	16 (89%)	2 (11%)
Carrier testing as part of prenatal coverage?	*Commercials*	1 (2%)	48 (94%)	2 (4%)
	HMOs	0 (10%)	20 (87%)	3 (13%)
	BC/BS plans-U	1 (13%)	27 (94%)	1 (13%)
	BC/BS plans-M	1 (6%)	15 (83%)	2 (11%)
Genetic testing as part of applicant screening?	*Commercials*	0 (0%)	49 (96%)	2 (4%)
	HMOs	0 (0%)	20 (87%)	3 (13%)
	BC/BS plans-U	0 (0%)	28 (97%)	1 (3%)
	BC/BS plans-M	0 (0%)	16 (89%)	2 (11%)
Genetic counseling of carriers who are covered?	*Commercials*	0 (0%)	49 (96%)	2 (4%)
	HMOs	1 (4%)	19 (83%)	3 (13%)
	BC/BS plans-U	1 (3%)	27 (94%)	1 (3%)
	BC/BS plans-M	0 (0%)	16 (89%)	2 (11%)

[a]Percentages may not add to 100 due to rounding.
[b]BC/BS plans-U represents the underwriter population and BC/BS plans-M, the medical director population.
SOURCE: Office of Technology Assessment, 1992.

Medical directors from 4 of 18 BC/BS plans responded that it was "'somewhat likely' that claims payment practices would be altered as new genetic tests came on line. However, nine medical directors from BC/BS plans thought it was "somewhat unlikely' that payment practices would be altered. In 10 years, seven underwriters from BC/BS plans thought it was "somewhat likely" and six thought it was "somewhat unlikely" (table 4-4).

Seven of 23 HMOS thought it was "very likely" or "somewhat likely" that they would alter their claims payment practices as new genetic tests came on line, nine HMOS thought it would be "very unlikely" and five responded it would be "somewhat unlikely. " In 10 years, only two HMOs thought it would be "very likely" they would alter claims payment practices, five HMOS responded it would be 'somewhat likely, ' eight thought it would be "somewhat unlikely" and five thought it would be "very unlikely."

CHAPTER 4 REFERENCES

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Table 4-4—Projected Reimbursement Practices by Insurers in 5 and 10 Years

Question	Respondent	Very likely	Somewhat likely	Somewhat unlikely	Very unlikely	No response[a]
How likely do you think it is that your company/HMO will in the next 5 years:						
Alter claims payment practices as new genetic tests come on line	*Commercials*	7 (14%)	12 (24%)	16 (31%)	16 (31%)	0 (0%)
	HMOs	1 (4%)	5 (22%)	9 (39%)	6 (26%)	2 (9%)
	BC/BS plans-U[b]	1 (5%)	10 (34%)	9 (31%)	7 (24%)	2 (6%)
	BC/BS plans-M	1 (6%)	4 (22%)	9 (50%)	2 (11%)	2 (11%)
In the next 10 years:						
Alter claims payment practices as new genetic tests come on line	*Commercials*	7 (14%)	12 (24%)	16 (31%)	16 (31%)	0 (0%)
	HMOs	1 (4%)	5 (22%)	9 (26%)	6 (26%)	2 (9%)
	BC/BS plans-U	6 (22%)	11 (38%)	3 (10%)	7 (24%)	2 (6%)
	BC/BS plans-M	1 (6%)	7 (39%)	6 (33%)	2 (11%)	2 (11%)

[a]Percentages may not add to 100 due to rounding.
[b]BC/BS plans-U represents the underwriter population and BC/BS plans-M, the medical director population.

SOURCE: Office of Technology Assessment, 1992.

Table 7-5—Economic Analyses of Genetic Tests and Genetic Counseling by Insurers

Question	Respondent	Yes	No	No response[a]
Has your company ever conducted an economic analysis of:				
Carrier testing as part of applicant screening?	*Commercials*	0 (0%)	50 (98%)	1 (2%)
	HMOs	0 (0%)	20 (87%)	3 (13%)
	BC/BS plans	0 (0%)	28 (94%)	1 (3%)
Carrier testing as part of prenatal coverage?	*Commercials*	1 (2%)	48 (94%)	2 (4%)
	HMOs	0 (10%)	20 (87%)	3 (13%)
	BC/BS plans	1 (13%)	27 (94%)	1 (13%)
Genetic testing as part of applicant screening?	*Commercials*	0 (0%)	49 (96%)	2 (4%)
	HMOs	0 (0%)	20 (87%)	3 (13%)
	BC/BS plans	0 (0%)	28 (97%)	1 (3%)
Genetic counseling of carriers who are covered?	*Commercials*	0 (0%)	49 (96%)	2 (4%)
	HMOs	1 (4%)	19 (83%)	3 (13%)
	BC/BS plans	1 (3%)	27 (94%)	1 (3%)

[a]Percentages may not add to 100 due to rounding.

SOURCE: Office of Technology Assessment, 1992.

into the costs and benefits of providing carrier screening or genetic counseling as part of a benefits package.

REIMBURSEMENT FOR GENETIC SERVICES—OTA SURVEY RESULTS

Will insurers pay for voluntary screening and followup counseling? And will insurance companies authorize payment for prenatal screening or testing of newborn children? Answers to these questions carry significant cost implications. They also will likely affect the degree to which carrier screening for CF becomes commonplace, since many people will be unwilling to pay out-of-pocket costs for the assays.

Insurance industry representatives assert that companies will not pay for most genetic tests unless they are "medically indicated." Thus, many health insurance companies do not pay for what they consider to be "screening" tests (28). Currently, the trend is toward closer evaluation of tests' medical necessity before insurance companies agree to pay for them. For example, a BC/BS task force evaluates 30 or 40 different procedures and devices each year and shares the results with the 73 independent BC/BS plans, each of which makes its own decisions about reimbursement (4).

More broadly, an increasing number of health insurance plans require that patients receive approval for procedures, including diagnostic tests, before the company will reimburse the cost. As more people become aware of carrier screening for CF, insurance companies are likely to receive more requests for reimbursement. In addition to uncertainty about reimbursement for the test, uncertainty also exists as to who will pay for the genetic counseling that must accompany CF carrier screening. Third-party insurers often have a policy of not reimbursing for counseling unless performed by physicians, which means the costs are reimbursed as general medical consultation fees or absorbed as part of costs on research grants (28).

From the perspective of the commercial laboratory that provides genetic tests to medical providers and patients, the issue of reimbursement is crucial to the level of their potential business—current and future. Few efforts have been made to assess the degree that CF carrier screening is being reimbursed by insurers and self-funded companies, but some individuals have been successful in obtaining reimbursement even in the absence of family history.

One private genetic service provider surveyed 66 patients about this issue in February 1991, and 27 responded (40 percent). After CF carrier screening, each patient had been given a letter explaining the CF carrier assay to submit with their claim. Third-party payors covered all costs of CF carrier screening for 11 of the 27 patients who responded; costs for 5 patients were covered in part and 11 received no reimbursement. Three of the eleven patients who received no reimbursement did not submit the letter to their insurer (9). Two individuals who were

originally denied coverage appealed the decision and received full coverage. All patients who were partially covered had 80 percent coverage or had not yet met their deductible, which is compatible with CF carrier screening being treated as a compensable procedure. While the survey data represent a small sample size at one clinic, the information collected shows that some patients have obtained reimbursement when CF mutation analysis is done for screening purposes.

On balance, however, it appears that, for now, if no medical indication for the test exists, a third-party payor generally will not pay for the assay. However, an appeal can usually be made and is sometimes successful for CF carrier screening when the specifics of mutation frequencies are documented (2). Nevertheless, lack of reimbursement is likely to influence the number of individuals who opt to be screened. Thus, the concept of medical necessity is particularly important to CF carrier screening and revolves around the issue of standards of care (ch. 5); insurers are likely to continue refraining from reimbursement for tests not judged to be customary physician practice. If CF carrier screening becomes commonplace, especially in the context of obstetric/prenatal care, the current situation of third-party payment for CF mutation assay could change.

To analyze the extent to which genetic tests and services were being, or might be, reimbursed by third-party payors, OTA collected data from three populations: genetic counselors and nurses in genetics, health insurers, and State Medicaid directors.

Experiences of Genetic Counselors and Nurses

In June 1991, members of the National Society of Genetic Counselors and the International Society of Nurses in Genetics who said they were currently in clinical practice were asked about the health care coverage of their patients (30). Approximately half of the respondents (198 respondents, 51 percent) reported that their patients have health care coverage very often or always (defined as between 75 and 100 percent of their patients). However, 43 respondents (11 percent) said that their patients sometimes or seldom if ever had coverage (between 0 and 50 percent of their patients).

Survey respondents were asked to recount their experience with reimbursement for various genetic services they performed. For general genetic counseling services, 22 (5 percent) responded they seldom if ever were covered, 56 (13 percent) said they sometimes were covered, 53 (12 percent) said they often were covered, 42 (10 percent) said they very often were covered, and 67 (16 percent) said they almost always were covered.

Where there was a positive family history for CF, genetic counseling was reported to be seldom if ever covered by 17 respondents (4 percent), sometimes covered and often covered by 86 (20 percent), very often covered by 26 (6 percent), and almost always covered by 65 (15 percent) respondents. Where there was no family history for CF, genetic counseling was reported to be seldom if ever covered by 35 respondents (8 percent), sometimes or often covered by 69 respondents (16 percent), very often covered by 10 respondents (3 percent), and almost always covered by 16 respondents (4 percent).

When asked if they knew of a patient's insurance claims for DNA analysis being rejected, 96 respondents (27 percent) said that they knew of such denials. One respondent to OTA's 1991 survey of genetic counselors and nurse geneticists gave this reason for the denial of a client's claim:

> In one family, the husband had an affected first cousin. This insurance would not pay for his screening because it is only a risk if the woman is a carrier and that the father's carrier status did not affect the pregnancy.

It is clear in this case that the insurance company falsely assumed that the father's carrier status was not relevant to the condition. At least two other surveys were conducted recently that also dealt with the issue of reimbursement for genetic screening services (1,19). One of these found a majority of respondents obtained full or partial reimbursement for CF mutation analysis. Reimbursement was more likely if a pregnancy was involved or when there was a family history of CF (1).

Health Insurers' Approaches

OTA's survey of health insurers inquired whether certain genetic tests or services—again, for individual and medically underwritten groups—are covered "at patient request" (no family history, i.e., screening), "only if medically indicated" (family history), or "not covered." No commercial company reimburses for CF carrier tests for screening purposes. The survey also found that carrier tests for CF—as well as Tay-Sachs and sickle cell (31)—are not

covered for any reason by 12 of 29 commercial insurers that offer individual coverage. Twelve respondents (41 percent) cover CF carrier assays if medically indicated. With respect to prenatal tests for CF, about 41 percent (12 respondents) that write individual policies reimburse for such tests when medically indicated (table 7-6).

For the 37 commercial companies offering medically underwritten group policies, carrier tests for CF (and, again, sickle cell or Tay-Sachs (31)) are not covered by any company when done solely at patient request. CF mutation analysis is covered by 24 of 37 companies if medically indicated. Ten companies offering medically underwritten group coverage do not cover any of the carrier or prenatal tests in the OTA survey. Sixty-two percent of companies (23 respondents) that offer medically underwritten group policies cover prenatal tests for CF (table 7-6).

Two of 25 BC/BS plans offering individual coverage would reimburse CF carrier screening at patient request. Sixteen of these BC/BS plans (64 percent) cover them if they are medically indicated and seven do not cover them. For prenatal tests for CF, 3 of these companies cover them at a patient's request, 19 if medically indicated, and 3 not at all. Of 21 BC/BS plans offering coverage to medically underwritten groups, CF carrier screening is covered at patient request by 2 companies (10 percent), only if medically indicated by 11 companies (52 percent), and not at all by 8 companies (38 percent) (table 7-6). Data for reimbursement for prenatal CF tests by BC/BS companies that medically underwrite groups are also presented in table 7-6.

Of the 11 HMOs that offer health insurance under individual policies, 1 respondent (9 percent) covers CF carrier tests at patients' requests and 7 HMOs (64 percent) reimburse for them if medically indicated. For the 20 HMOs that offer medically underwritten group contracts, 1 HMO (5 percent) covers CF carrier tests at patients' request, 13 respondents (45 percent) reimburse for them if medically indicated, and 2 (10 percent) do not cover them at all. Table 7-6 presents these results as well as how HMOs cover prenatal tests for CF.

OTA's survey results reveal that carrier and prenatal tests often are not covered under individual and medically underwritten group policies unless they are medically necessary—i.e., a family history exists. Such lack of reimbursement could have a

Table 7-6—Reimbursement for Cystic Fibrosis Carrier Tests and Genetic Counseling

Question: Do your standard individual policies and medically underwritten policies provide coverage for:

	Respondent	At patient request	Medically indicated only	Not covered	No response[a]
Individual policies					
Carrier tests for CF?	*Commercials*	0 (0%)	12 (41%)	12 (41%)	5 (17%)
	HMOs	2 (18%)	7 (64%)	0 (0%)	2 (18%)
	BC/BS plans[b]	2 (8%)	16 (64%)	7 (28%)	0 (0%)
Prenatal tests for CF?	*Commercials*	0 (0%)	12 (41%)	14 (48%)	3 (10%)
	HMOs	1 (9%)	7 (64%)	1 (9%)	2 (18%)
	BC/BS plans	3 (12%)	19 (76%)	3 (12%)	0 (0%)
Genetic counseling?	*Commercials*	2 (7%)	6 (21%)	18 (62%)	3 (10%)
	HMOs	1 (9%)	6 (55%)	1 (9%)	3 (27%)
	BC/BS plans	1 (4%)	9 (36%)	13 (52%)	2 (8%)
Medically underwritten policies					
Carrier tests for CF?	*Commercials*	0 (0%)	24 (65%)	10 (27%)	3 (8%)
	HMOs	1 (5%)	13 (65%)	2 (10%)	4 (20%)
	BC/BS plans	2 (10%)	11 (52%)	8 (38%)	0 (0%)
Prenatal tests for CF?	*Commercials*	1 (3%)	23 (62%)	10 (27%)	3 (8%)
	HMOs	2 (10%)	14 (70%)	0 (0%)	4 (20%)
	BC/BS plans	3 (14%)	14 (67%)	4 (19%)	0 (0%)
Genetic counseling?	*Commercials*	2 (5%)	16 (43%)	17 (46%)	2 (5%)
	HMOs	2 (10%)	12 (60%)	1 (5%)	5 (25%)
	BC/BS plans	1 (5%)	7 (33%)	12 (57%)	1 (5%)

[a]Percentages may not add to 100 due to rounding.
[b]OTA also inquired about reimbursement practices for BC/BS open enrollment nongroup polices and reports these data elsewhere (31).

SOURCE: Office of Technology Assessment, 1992.

significant impact on the ultimate utilization of CF mutation analysis.

OTA found that genetic counseling was not covered by 18 of 29 commercial companies offering individual coverage and 17 of 37 offering medically underwritten group coverage. Six insurance companies offering individual policies and 16 that medically underwrite groups cover genetic counseling only if it is medically indicated. Two companies offering each type of coverage will reimburse for genetic counseling at the patient's request (table 7-6). Similar results for BC/BS plans and HMOs are also presented in table 7-6.

Finally, respondents were asked to indicate whether they agreed or disagreed with the following scenario:

> Through prior genetic testing, the husband is known to be a carrier for CF. Before having children, the wife seeks genetic testing for CF. The insurance company declines to pay for the testing, since there is no history of CF in her family.

For commercial insurers, 21 medical directors (41 percent) agreed strongly or somewhat. Twenty-nine respondents (47 percent) disagreed somewhat or strongly with this scenario. For respondents from BC/BS plans, 12 agreed strongly or somewhat (41 percent) and 15 disagreed strongly or somewhat (52 percent). Four respondents from HMOs (17 percent) agree somewhat compared to 17 who disagreed somewhat or strongly (74 percent). These results indicate that insurers are split in their attitudes (or in their understanding of genetics) towards financing CF carrier screening as a part of reproductive decisionmaking.

Medicaid Reimbursement

For some low income citizens, Medicaid provides access to genetic tests and genetic counseling. Medicaid reimbursement for genetics and pregnancy-related services has been reported to vary from State to State (34). To examine the current state of such reimbursement, OTA surveyed directors of State Medicaid programs in June 1991 to assess which of seven services—amniocentesis, ultrasound, chorionic villus sampling (CVS), maternal serum alpha-fetoprotein (MSAFP) tests, DNA analysis, chromosomal analysis, and genetic counseling—were covered. OTA also asked for information about reimbursement amounts for each service.

Respondents were asked to indicate if their State guidelines stipulated whether a procedure was "covered," "not covered," "coverage based on individual consideration," or "unknown." There was no attempt to determine how completely these guidelines were followed by each State, and there have been reports that people have experienced difficulties in getting any Medicaid reimbursement for the types of services OTA inquired about (29). In total, 47 States and the District of Columbia responded (94 percent response rate). Two States responded to OTA's survey, but are not included in this analysis. Arizona's program differs from all other States, and OTA could not obtain comparable data for it. Connecticut returned a survey, but said budget restraints precluded it from completing the survey.

State coverage of genetic procedures clearly varies (tables 7-7, 7-8). Of the 46 States[3] in the analysis, 45 cover amniocentesis, with an average reimbursement of $59.32. Fetal ultrasound is covered in 44 of 46 States, with 2 States covering it only by individual consideration. The average reimbursement for fetal ultrasound is $83.13. CVS is covered by 31 States (67 percent) and not covered in 10 States (22 percent), with 1 State reporting unknown coverage and 4 States reporting individual consideration only. The average reimbursement for CVS is $145.90. MSAFP testing is covered in 44 States and by individual consideration in 2 States. Average reimbursement for MSAFP is $21.76.

DNA analysis is covered by 26 States (57 percent) and not covered in 6 States (13 percent), with unknown coverage in 8 States (17 percent) and 6 States (13 percent) covering it based on individual consideration. Average reported reimbursement for DNA analysis is $33.39. Chromosome analysis, from amniotic fluid or chorionic villus, is covered by 41 States (89 percent), not covered by 1 State, with 4 States (9 percent) reporting individual consideration only. Average reimbursement for chromosome analysis is $235.68.

Whether the State covered genetic counseling clearly posed the most difficult question for Medicaid program directors. A substantial percentage indicated that if the service were coded as an office

[3] Hereinafter, "States" refers to the 45 States and the District of Columbia that completed a questionnaire used in OTA's analysis.

Table 7-7—Medicaid Reimbursement for Genetic Procedures By State

State	Amniocentesis	Ultrasound	Chorionic villus sampling	Maternal serum alpha-fetoprotein	DNA analysis	Chromosome analysis	Genetic counseling
Alabama	$ 45.00	$ 58.50	Not covered	$19.60	$ 24.34	$199.99	Not covered
Alaska	220.00	126.00	$100.00	24.00	31.00	270.00	Covered if part of office visit
Arizona	Managed care plans offer different coverages. See text for explanation.						
Arkansas	49.16	54.62	Covered[a]	34.00	29.50	275.21	Not covered
California	46.94	80.98	Not covered	12.03	Not covered	273.18	$200.56 complete 133.40 interim 100.28 followup
Colorado	167.00	103.00	112.00	24.28	29.25	275.12	Not covered
Connecticut	Questionnaire not completed due to budgetary constraints.						
Delaware	Did not respond.						
District of Columbia	41.00	100.71	44.65	15.87	?	80.00	Not covered
Florida	23.00	137.00	23.00	24.50	14.50	243.50	Not covered
Georgia	107.00	80.00	Covered[a]	6.85	Not covered	28.69	Not covered
Hawaii	75.60	81.25	Covered[a]	23.52	?	164.50[b]	Covered if part of office visit
Idaho	41.90	88.90	Covered[a]	26.55	Covered[a]	281.83	Not covered
Illinois	59.95	70.65	105.00[b]	24.41	14.40	87.10	Not covered
Indiana	[b]	[b]	[b]	[b]	[b]	[b]	Not covered
Iowa	56.58	84.17	71.84	22.11	30.57	278.69	52.15/15 minutes
Kansas	100.00	120.00	Not covered	20.25	Not covered	Not covered	Not covered
Kentucky	75.00-100.00	97.50-130.00	375.00-500.00	24.41[b]	29.50[b]	268.94[b]	100.00-300.00[b]
Louisiana	39.48	80.00	Not covered	15.70	?	275.21	?
Maine	23.00	25.30-59.40	101.80	15.00	?	251.00	Covered as part of office visit
Maryland	31.00	56.00	31.00	27.26	54.00	215.25	13.00-40.50
Massachusetts	49.43	92.00	481.07	16.73	24.76	225.73	Covered if part of office visit
Michigan	36.80	66.12	358.17	20.60	?	167.31	Covered as part of office visit; 11.00-54.00
Minnesota	55.00	70.00	153.00	25.28	30.57	278.71	75% of office visit rates
Mississippi	41.90	69.30	Not covered	6.15	Not covered	260.56	Not covered
Missouri	25.00	65.00	Not covered	24.41	16.43	150.00	Not covered
Montana	51.91	68.68	65.2% of charges	42.30	?	309.79	Covered if part of office visit
Nebraska	Did not respond.						
Nevada	69.70	152.36	Covered[a]	42.89-55.76	[b]	400-520	47.46-156.66
New Hampshire	25.00	64.00	[b]	14.00	29.00	14.00	[b]
New Jersey	37.00	55.00	Not covered	10.20	[b]	230.00	Covered[a]
New Mexico	59.60	52.87	?	23.41	29.50[b]	268.50[b]	Not covered
New York	20.00	55.00	Covered[a]	6.50	31.39	90.00	Covered[a]
North Carolina	119.20	73.44[b]	Not covered	20.80	Not covered	297.65	Not covered
North Dakota	39.28	109.93	52.20	21.73	110.49	239.42	Not covered
Ohio	75.00-98.00	95.77-102.65	250.00-402.00	24.41	[b]	268.94	16.88-20.00
Oklahoma	59.50	92.70	Not covered	24.41	Covered[a]	268.93	Not covered
Oregon	44.48	74.82	38.05	22.94	Covered[a]	268.93	Covered if part of office visit
Pennsylvania	50.00	97.50	59.00	20.00	14.50-30.80	275.20	Covered if part of office visit; 30.00-49.00
Rhode Island	Did not respond.						
South Carolina	31.80	66.00	75.00	6.20	28.50	300.00	Not covered
South Dakota	63.00	100.00	50% of usual and customary charges	24.41	29.50	275.21	?
Tennessee	57.00-60.00	51.00-88.00	178.75	24.98	109.68	275.21	Covered[a]
Texas	81.22	116.41	94.82	23.77	?	200.00	100.00 initial 25.00 followup
Utah	46.45	47.29	111.60	20.87	11.86	Covered[a]	Covered if part of office visit
Vermont	22.00	75.00	Not covered	25.00	Not covered	400.00	Not covered
Virginia	110.00	90.00	66.00	25.00	10.50	135.00	Covered if part of office visit
Washington	31.54	61.10	Covered[a]	24.38	Covered[a]	251.91	Not covered
West Virginia	43.00	36.00	[b]	24.98	20.97-31.39	275.20	Covered if part of office visit; 10.00
Wisconsin	47.64	115.68	189.40	24.13	Covered[a]	281.47	Covered[a]
Wyoming	50.00	127.95	Covered[a]	22.00	?	198.00	?

[a]No dollar amount reported to OTA.
[b]Individual consideration.
?Respondent did not indicate whether explicitly covered or not.

SOURCE: Office of Technology Assessment, 1992.

Table 7-8—Average Medicaid Reimbursement for Genetic Procedures

	Amniocentesis	Ultrasound	Chorionic villus sampling	Maternal serum alpha-fetoprotein	DNA analysis	Chromosome analysis	Genetic counseling
Number of States reporting dollar amounts of reimbursement.....	45	45	22	45	2	43	10
Average amount reimbursed....	$59.32	$83.13	$145.90	$21.76	$33.39	$235.68	$68.87

SOURCE: Office of Technology Assessment, 1992.

visit or consultation, it might be covered; in such cases, however, the service of genetic counseling is hidden in a general visit code. Eleven States (24 percent) reported covering genetic counseling; 11 (24 percent) reported covering it only if part of an office visit or consultation; 19 States (41 percent) do not cover genetic counseling, 2 States cover it by individual consideration, and 3 States (7 percent) reported unknown coverage. The average reimbursement amount, in large measure, reflects the range of reimbursements for different levels of office visits. As such, the average amount given ($68.87) cannot be viewed as accurate for genetic counseling services only. It should also be noted that "family DNA testing" is covered in some States (e.g., New York).

In addition to finding that some States do not cover certain services, the survey indicates the amounts reimbursed by States that do pay fall well short of charges for the procedures (5,23) (ch. 9). Hence, genetic service providers that accept Medicaid patients must subsidize the costs.

SUMMARY AND CONCLUSIONS

Because the U.S. insurance industry is not homogeneous in its composition and policies, interest in new technologies (e.g., CF carrier screening) will vary according to both the type of insuring entity and the specific company or plan involved. The majority of the insured U.S. population obtains health insurance through the workplace under group policies. Such policies do not require diagnostic tests or physical examinations. Some Americans, however, obtain health insurance through medically underwritten group policies or obtain it on an individual basis. These individuals typically undergo risk classification and might pay higher rates. Yet little data exist on how commercial insurers, Blue Cross and Blue Shield plans, and health maintenance organizations factor genetic tests in the risk classification process. Chapter 8 reports OTA survey data related to this issue.

How insurers view genetic tests, generically, might affect their utilization. OTA's 1991 survey of commercial insurers, BC/BS plans, and HMOs that offer individual policies or medically underwrite groups sheds some light on how these populations view genetic tests, generally, and CF carrier tests, specifically. Clearly, they want the option of determining how to use genetic tests in determining risks. OTA's survey also found that insurers generally agree that it is fair for them to use genetic tests to identify persons with increased risk of disease.

Finally, the issue of who pays for CF carrier tests, prenatal tests for CF, and genetic counseling is important to the frequency at which people will opt for CF carrier screening. OTA survey results indicate that the costs of carrier tests or prenatal tests for CF (as well as sickle cell anemia and Tay-Sachs) are rarely covered by an insurer when carried out at the patient's request. Insurers either covered those costs when medically indicated (family history) or not at all. With respect to public financing for genetic tests, OTA surveyed State Medicaid directors to determine which services were covered and at what levels. Medicaid reimbursement for genetic services varies widely from State to State and does not approach full reimbursement of the actual amount charged for the service.

CHAPTER 7 REFERENCES

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Goodwin, Suzanne (NIH/OD)

From: Laila Morris [laila.morris@ucdmc.ucdavis.edu]
Sent: Friday, April 29, 2005 1:20 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: SACGHS report public comment

I have read the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) report on coverage and reimbursement of genetic tests and services.

I was pleased that the report recognized certified genetic counselors as healthcare professionals uniquely trained and qualified to provide genetic services and for their services to be covered and/or reimbursed by payers. However, there was a matter that was disappointing in the report. It did not recommend that the American Board of Genetic Counseling (ABGC) board exam certification was an important and essential safety standard in order to provide genetic counseling services.

In my 13 year career as a genetic counselor, I have worked in 4 different states: New York, New Jersey, Connecticut and most recently, California. Only California has a state standard administered by our state department of health services for genetic counseling. Essentially the California standard requires that only genetic counselors who have attended an accredited master's degree training program and who are eligible to sit or have passed the ABGC exam are able to provide genetic counseling services. Someday soon, California will also have a state licensing requirement, which will essentially mirror the ABGC requirements. As a resident of California, I feel that our public is uniquely protected from untrained and inexperienced individuals hanging up a shingle to call themselves a genetic counselor and then hand out inaccurate or blatantly incorrect information. This situation is a reality in many other states.

The SACGHS report has the opportunity to recommend a national genetic counseling standard, which recognizes that the ABGC credential is an important standard and qualification for those providing these services and their coverage/reimbursement by payers. As a ABGC-certified genetic counselor, I feel that we are the health care professionals dedicated to provide genetic counseling services and it is important we are distinctly recognized as qualified providers of these services.

Thank you.

Laila Rhee Morris, MS
Genetic Counselor
ABGC Certified, 93124

Laila Rhee Morris, MS
Genetic Counselor, Certified, ABGC
UC Davis, Department of OB/GYN
phone: (916) 734-6124
email: laila.morris@ucdmc.ucdavis.edu

THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON
MEDICAL SCHOOL

DEPARTMENT OF OBSTETRICS, GYNECOLOGY, & REPRODUCTIVE SCIENCES
LYNDON B. JOHNSON GENERAL HOSPITAL

5656 Kelley Street
Houston, Texas 77026

713 566 5926
713 566 4521 fax

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892
Email: goodwins@od.nih.gov
Fax: 301-496-9839

May 4, 2005

Dear Ms. Goodwin:

I am writing in regards to the SACGHS Draft Report on Coverage and Reimbursement of Genetic Tests and Services. I am a genetic counselor practicing in a county hospital. I often find myself struggling with the barriers placed upon my practice by the limitations genetic counselors face in being reimbursed for the services that we provide.

I applaud the SACGHS's efforts to elucidate the importance of medical genetic services and the unique reimbursement issues that practitioners such as myself face. I would like, however, to strongly encourage your committee to consider the following revisions to your draft in preparation of your final report:

1 – Genetic counselors are **not** statutorily eligible to bill Medicare for the services we provide. While this point can be inferred from the text of your draft as it stands, I believe that it is in the committee's best interest to make this point specifically. Many practitioners of genetics (i.e. MD geneticists, nurse geneticists) are recognized providers per Medicare; making the point that such a large segment of providers, namely genetic counselors, are not, will help to seal the gravity of the reimbursement issues you discuss.

2 – The statement regarding establishing a mechanism to later determine which providers have the credentials necessary to be considered as reimbursable providers of genetic counseling services is, as it should be, inclusive of all providers of genetic counseling services. I appreciate the advisory committee's desire not to leave any potential providers out of its recommendations. However, I will point out that genetic counselors, in particular, already have the appropriate credentials and training necessary to provide genetic counseling services. Given that we do comprise such a large percentage of

genetic health care providers, I feel that our profession and its credentialing process should be particularly recognized. I see no reason not to point out genetic counselors as reimbursable providers, with the caveat that other eligible providers should be further identified and included in future efforts.

Thank you for the opportunity to comment on the advisory group's efforts. I, for one, appreciate the work the group has done on behalf of all genetic service providers. I hope that the advisory group will recognize, however, that the final report has the potential for impacting decisions made both by the government and by private payors. By more clearly specifying the hurdles to reimbursement faced by genetic counselors, a group that provides a large percentage of the medical genetic counseling services discussed in your draft, this document will better arm all genetic health care providers in making their pleas for better reimbursement in both the public and private health care sectors.

Sincerely,

Sarah Jane Noblin, MS, CGC
Certified Genetic Counselor

4430 Fairview Road
Reno, NV 89511
May 3, 2005

Secretary's Advisory Committee on Genetics, Health, and Society
c/o Suzanne Goodwin
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin,

I am writing to comment on the draft recommendations of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) regarding coverage and reimbursement for genetic testing and services. Please forward my comments to the committee

I appreciate the hard work of the committee in tackling the difficult issues of coverage and reimbursement, and thereby, accessibility of genetic testing and services. I also appreciate the committee's support for genetic counseling services. My comments specifically relate to genetic counseling services and reimbursement.

I urge the committee to recommend that American Board of Genetic Counseling (ABGC)-certified genetic counselors (and GNCC genetic nurses) be recognized as qualified health professionals, who have the authority to bill independently for genetic counseling services.

I am a certified genetic counselor in a unique situation. I am the only certified genetic counselor in Northern Nevada (Reno), accessible to a population of about half a million people. I think I am the only certified genetic counselor that provides hereditary cancer risk assessment and counseling in this state. I came to Reno to work with a perinatalogist. Eventually, I went into private practice, because of circumstances beyond my control, in order to continue providing genetic counseling services to this community. There is very little professional respect for genetic services in this community and state. The State contracts with one M.D. geneticist, in Las Vegas, to service the entire state. It takes months to get an appointment with her, and she is necessarily very selective in who gets an appointment. I have a Ph.D. in Developmental Biology. That has probably contributed to my ability to become a provider for some local insurances. I have always presented myself as a certified genetic counselor, who happens to have a Ph.D. A few insurers, for whom I am a provider, recognize me as a genetic counselor. Frequently, however, I am portrayed to subscribers as a mental health provider, and that I provide mental health counseling. I have tried to correct these insurers about my services, to no avail. Just last week, after numerous email communications, I was informed by an insurer, for whom I am a provider, that my choices are: 1) to be listed as a mental health provider, with psychology as my specialty, or, 2) not be listed. Another insurer, for whom I am a provider, only covers my services if the patient is a pregnant female. This excludes reimbursement for my services for preconceptional genetic counseling, or hereditary cancer risk assessment and counseling. Sometimes, whether I am reimbursed by an insurer depends on whether 'genetic counseling' is a specific plan's covered benefit, although I am a provider for that insurer.

In my opinion, it doesn't make sense to only allow a genetic counselor to bill through a supervising physician, who relies on the genetic counselor to provide adequate genetic counseling because he/she (the supervising physician) knows little about the intricacies of genetics. The genetic counselor, who is non-directive by training, may have to acquire the more directive stance of the supervising physician

when counseling patients. I do not have a supervising physician, and I am very careful in knowing my professional limits.

I am passionate about genetics, and dedicated to bringing genetic services to the people of this community. It's a struggle that causes me much emotional pain. I am not even close to being financially independent. Genetic services are largely unregulated. Anyone can say that he/she is a genetic counselor and/or provides genetic counseling services. Physicians, with very little formal training in genetics, and no interest or understanding of the complexities of genetics, or the ethical issues raised in genetics, record "genetic counseling provided" in a patient's medical record. I may spend 10-times longer providing genetic counseling, and write a two to four page consult letter. A physician can bill for 'genetic counseling.' Often, I cannot. The physician recovers three to five-fold more than the discounted, out-of-pocket fee I charge for a genetic counseling appointment. I've heard some incredibly unknowledgeable statements from physician specialists regarding genetic issues. For example, that genetic counseling regarding hereditary breast cancer is not indicated for a young, affected woman because she has no daughters.

The 2000 Report and 2001 Recommendations of the Nevada Maternal and Child Health Advisory Board to the Governor states that "In order to develop statewide genetic services and promote such services in private practice, the Board recommends that genetic counselors be authorized as non-physician providers for Medicaid." This never happened. I have been unable to learn from State officials why this never happened. I'm guessing—consistent with my experiences with the State—that provision of genetic services is a low budgetary priority. I am not reimbursed by Medicare.

In addition to genetic counselor independent billing and reimbursement, I support the derivation of CPT codes that reflect the long sessions that we may have with patients when providing genetic counseling services. It is not unusual for a genetic counselor to spend 90 minutes or more in a counseling session. A shorter session may not adequately meet the needs of the patient, and may not adequately inform the patient of his/her options.

You may know that genetic counselors are pursuing licensure on a state-by-state basis. I think, that it will be a long, long time before genetic counselors are licensed in Nevada. To help genetic counselors gain medical professional recognition, I urge the committee to include genetic counselors as non-physician health providers with national provider identifiers.

To quote from the conclusion of a recent medical journal article relating to direct-to-consumer advertising of genetic tests, "...providers and payers need to consider the delivery of genetic services and genetic education for persons at all risk levels" (Genetics in Medicine. 2005;7(3):191-197).

I am hoping that your recognition and support for genetic counselors and genetic counselor billing and reimbursement, raises the status of genetic counseling, everywhere. Patients and the public will benefit.

For genetic services for the people of Nevada,

Robbin Palmer, Ph.D.
Certified Genetic Counselor

cc: Kelly Ormond, M.S.
President, National Society of Genetic Counselors

Pamela Petschke [pampetschke@hotmail.com]

Coverage and Reimbursement of Genetic Tests and Services
Response to Public Comment Draft

1. Clearly, the novelty and predictive nature of genetic testing presents unique challenges to the traditional coverage decision-making process. For this reason, I *support* the recommendation to "task an appropriate group or body to develop a set of principles to guide coverage decision making for genetic tests." These principles should address the unique challenges presented by genetic testing (prevention, rare disease tests, therapeutic versus informational benefit, etc.) and their primary function should be to outline specific criteria that could be used by decision makers (of both public programs and private plans) to determine which types/categories of genetic tests should be covered, should not be covered, or fall into an uncertain "gray zone". Furthermore, given the current emphasis on evidence-based coverage decision-making, I *agree* that this appropriated group should also assess the existing evidence for specific genetic tests, identify any gaps in evidence, and fund studies to address such gaps. Finally, the recommendation makes reference to the EGAPP Work Group, stating that it "is performing similar work and, thus, is an example of such a body to be tasked to develop these principles and address these issues." After reading the subsequent description of the ACCE/EGAPP project, I am unclear as to how the work of this group differs from that of SACGHS's proposal. Thus, while I support the above recommendations, I question the necessity of creating a new task force if one conducting similar work already exists!

2. In theory, standardization of coverage decisions across public and private payers is ideal. Yet, with regard to Medicare and certain genetic tests, this may not be true. Many, if not most, hereditary diseases manifest prior to age 65 and genetic tests are often used for preventive purposes or for reproductive and/or life planning. For these reasons, the utility of certain genetic tests within the elderly population is questionable and Medicare often does not cover these tests. Although reasonable for the population served by Medicare, such coverage decisions are inappropriate for younger populations – most of whom are covered under private insurance plans. Unfortunately, many private plans based their coverage decisions on those of Medicare. Therefore, I agree that "private payers should be supported with necessary information to make their own coverage determinations" and I *strongly support* the recommendation that "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."

3. Although the current combination of national and local systems used by Medicare for coverage decision-making processes maximizes regional flexibility, variations among local coverage policies can cause confusion and create a sense of inequity among Medicare beneficiaries. Therefore, I *do not* advocate changing the current system but *do support* SACGHS's recommendation to "encourage CMS to move forward with the implementations 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." I am aware that this process could increase the number of non-coverage or limited coverage decisions at

the national level, but hope the opposite would be true. Given that Medicare decisions are closely followed by private health plans, I believe it is important to broaden rather than restrict national coverage of genetic tests and services.

4. As stated previously, I believe that Medicare's influence on private health plans necessitates the broadening of its national coverage for genetic testing. I was, in fact, surprised to read in the draft report that "of the approximately 274 national coverage decisions issued by CMS, *only one* relates to genetic tests and services". Therefore, I *strongly support* SACGHS's recommendation "that preventive services, including predispositional genetic tests and services, meeting evidence standards should be covered under Medicare".

5. With regard to Medicaid coverage, given that individual states are responsible for making coverage decisions about genetic tests and services, it seems only logical that state decision makers be provided with specific information necessary to make such decisions. Thus, I *support* the recommendation that "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." In fact, I am surprised that this information is not currently being provided! Furthermore, since coverage and payment rates are highly dependent on individual state budgets (which vary form year to year), I *agree* that "HHS should continue to provide states with grants that encourage the coverage, adoption, and provision of genetic services that have a sound evidence base" and suggest that HHS also provide states with a set of guidelines to help determine which tests must be dropped, if necessary, in times of financial hardship.

6. I understand the rational behind SACGHS's recommendation that "until the fee schedule can be reconsidered in a comprehensive way (i.e. the fee freeze is lifted), the Secretary should direct CMS to address variations in payment rates for the genetic test CPT codes through its inherent reasonableness authority". Yet, for reasons that I do not fully understand, the draft report acknowledges that the inherent reasonableness review process may result in a lower rather than a higher payment rate. Therefore, while I do not have enough information to suggest an alternate solution to the problem, I *cannot fully support* this recommendation.

7. Unlike many other laboratory tests, genetic tests raise complex legal, ethical, societal, psychological, familial, and personal issues that must be addressed through genetic counseling. Not surprisingly, as the number of relevant genetic tests has increased, so has the demand for genetic counseling services. Unfortunately patient access to genetic counseling could be limited by problems regarding the billing and reimbursement of these services. Of particular concern to me are inappropriate CTP payment codes and direct billing eligibility of non-physician genetic counselors.

- Adequate reimbursement for medical services is dependent, in part, on proper CTP codes. Since there are no specific CTP codes for genetic counseling, these services must be billed using generic evaluation and management (E&M) CPT codes. Given the unique nature of genetic counseling, however, this billing

procedure can be problematic. For example, genetic counseling sessions typically last between 2 and 3 hours but the highest-level CPT E&M code is for an 80-minute visit. This discrepancy results in inadequate reimbursement for the service provided. Therefore, I *strongly support* the recommendation that "HHS, with input from the various providers of genetic counseling services, should assess the adequacy of existing CPT E&M codes and their associated relative values with respect to genetic counseling services. Any inadequacies identified should be addressed as deemed appropriate." Furthermore, as the demand for genetic counseling services increases, HHS might find it necessary to abandon the use of E&M CPT codes all together and establish specific CPT codes for genetic counseling services.

- Another issue affecting the reimbursement of genetic counseling services is direct-billing eligibility for non-physician genetic counselors. Although a physician can provide genetic counseling services, many non-physician practitioners provided comparable, if not superior, (and less costly) services. Unfortunately, these practitioners are often inadequately reimbursed because they are unable to bill directly for their services and must bill "incident to" a supervising physician. In general, direct billing eligibility depends on the credentials and qualifications of the service provider. Unfortunately the credentials and criteria required for direct billing of genetic counseling services are unclear and vary from state to state and plan to plan. As a result, the vast majority of practitioners providing genetic counseling services do not bill directly for their services and, thus do not receive adequate reimbursement. This is unacceptable and must be remedied. Therefore, I *support* SACGHS's recommendation that "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." I expect that, if implemented, this would result in an increased number of qualified health providers allowed to bill directly for their services.

I believe that revisions to both the direct billing system and CPT payment codes will result in greater reimbursement for genetic counseling services, which, in turn, will ensure greater patient access to this undeniably necessary service.

8. With out a doubt, the genetic education and training of health care providers has a significant impact on the clinical use of (and thus coverage and reimbursement for) genetic testing. As we have seen with newly developed prescription drugs, newly developed genetic tests are increasingly being marked directly to consumers. And, as has been the case with prescription drugs, if health care providers are not adequately trained in genetics, they may provide (and expect coverage for) inappropriate services on behalf of their patients. Therefore, I *strongly agree* with SACGHS's conclusion that "there is a need to support the ongoing training and continued education of health providers in genetics and genomics" and I *support* the recommendation that "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. As mentioned previously, direct-to-consumer marketing has increased public awareness of genetic testing and, in turn, increased consumer demand. If this demand is fueled by accurate and reliable information, it could facilitate appropriate and timely coverage of new genetic tests and services. Consumer demand, however, can also be based on inaccurate and incomplete information that could result in inappropriate coverage decisions. For these reasons, I *strongly support* the recommendation that "the Secretary should leverage the HHS resources to develop and make widely available reliable and trustworthy information about family history, genetics, and genetic technologies to guide and promote informed decision making by healthcare consumers and providers." Furthermore, as a public school science teacher, I will continue to do my part to educate America's future consumers in the basic principles of genetics, genetic testing, and its accompanying ethical, legal, and social issues.

Goodwin, Suzanne (NIH/OD)

From: Barbara Pettersen [barbpett@bendcable.com]
Sent: Friday, April 22, 2005 2:18 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: comment on SAGHS reimbursement draft

Dear Ms. Goodwin and members of the SAGHS:

I am writing to comment on the (HHS) Secretary's Advisory Committee on Genetics, Health and Society draft recommendations on coverage and reimbursement for genetic counseling services; specifically, recommendation #7, regarding genetic counseling services and reimbursement issues. I am a genetic counselor with 20 years clinical experience, nationally certified by the American Board of Medical Genetics (ABMG) and American Board of Genetic Counseling (ABGC). I am currently in private practice doing cancer genetic counseling and am supervised by three local oncologists. Although they value my services, refer all appropriate patients for cancer genetic counseling and testing, and work with me to carry out necessary follow-up and medical management for these patients, they are not able to bill for me under their names ('incident to' billing), as genetic counselors are currently not accepted billing practitioners under CMS/Medicare.

Therefore, as I cannot bill "incident to" my supervising oncologists, and I cannot bill Medicare and most private insurance and HMO plans directly under my name, patients must pay for my services out-of-pocket without hope of insurance or Medicare reimbursement. This forces me to 1) maintain an unusually low fee schedule in order to make my services accessible to the majority of patients, and 2) to actually write off payments for patients who cannot afford my services. I am the ONLY genetic counselor within a 120 mile radius and the only health care practitioner with advanced training and expertise in cancer genetic risk assessment and genetic counseling. Without my presence in this regional medical community, which serves a population base of >150,000, patients who need genetic services would have to travel over 100 miles to an urban center for similar services. Unless billing practices for board certified genetic counselors are improved, I am, reluctantly and sadly, at the point of considering another career. With current billing restrictions, I cannot make a living wage doing what I'm trained to do.

I am writing to **strongly** encourage that the recommendations to the Secretary include ABGC certified genetic counselors as qualified providers who should have the ability to bill independently. This will allow me to maintain a full caseload, make a living wage, and continue to serve patients in my community, for which I am the sole local genetics provider.

I also support the remainder of the recommendations regarding genetic counseling service coverage and reimbursement, including the reimbursement of prolonged service codes both for direct and incident to billing. I also support the inclusion of non-physician health care providers eligible to directly bill health plans as eligible for national provider identifier. All of these measures would directly enable me to maintain a practice in a community with a proven need for local genetic services.

Sincerely,

Barbara J. Pettersen

Barbara J. Pettersen, MS, CGC
Genetic Counseling of Central Oregon
2607 NW Polarstar Ave.
Bend, OR 97701
541-419-0097
Fax 541-382-6362
barbpett@bendcable.com

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

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DEPARTMENT OF CLINICAL PHARMACY
SCHOOL OF PHARMACY
C-152, BOX 0622
UNIVERSITY OF CALIFORNIA
SAN FRANCISCO, CA 94143-0622

Telephone: (415) 476-2352

Date: April 29, 2005
Subj: Comments on SACGHS Report on Coverage and Reimbursement of Genetic Tests and Services

This is a very informative and well-written report.

Primary Comments

- The report only briefly touches on the complexities introduced because of the widespread use of laboratory-developed genetic tests ("home brews"). This issue is mentioned briefly in a footnote (p. 23) and some further discussion might be warranted. I will mention two key issues that emerge from the use of home brews. First, there are scant data available on such tests including how they are used and by whom. This presents a serious challenge to the recommendation for developing an evidence base for evaluating tests. Second, we have found in conversations with industry that the current coverage system can provide sometimes perverse and contradictory incentives to seek FDA approval. For example, companies may not have an incentive to seek FDA approval for genetic tests for small populations because they may be able to negotiate higher reimbursement rates directly with the users than if they had an FDA-approved test with coverage rates driven by CMS (which is thought to result in lower rates).

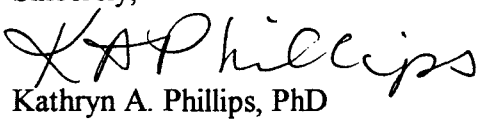
- The general issue of how to generate data to develop an evidence base could be expanded. The recommendation to develop a mechanism "that would specifically promote and fund studies to address any identified gaps in the evidence base" is vague (p 28). A key issue is that the FDA does not have a mandate to examine or require data on clinical utility, and the CMS does not have a mandate to consider the costs and benefits of tests. Thus, it will be a key challenge to determine how data to develop the evidence base can be obtained.

- The report identified a key issue: the application of the screening exclusion to genetic tests (p. 33). As noted, it is unclear whether tests such as the AmpliChip would be considered "screening" or "diagnostic". Thus, the recommendation that Medicare cover preventive services (p. 34) could focus more on the need to develop better definitions of what will be considered "diagnostic" testing and thus covered. Recommending that Medicare cover preventive services as a group may be a far-reaching and unrealistic recommendation.

Other Comments

- p. 24. The source for the coverage considerations in the box was not cited. Also, this list is missing cost-effectiveness (cost-effectiveness considerations are discussed on the next page). Although it mentions how much money the technology might save, that does not capture the consideration of whether the technology could provide better health outcomes for a reasonable cost (i.e., cost-effectiveness).

Sincerely,



Kathryn A. Phillips, PhD
Professor of Health Economics and Health Services Research
Director, Program in Pharmacogenomics and Population Screening
School of Pharmacy, Institute for Health Policy Studies, and UCSF Comprehensive Cancer Center
University of California, San Francisco
3333 California Street #420 Box 0613
San Francisco, CA 94143 (fedex 94118)
(415) 502-8271 fax (415) 502-0792
kathryn@itsa.ucsf.edu
http://www.ucsf.edu/clpharm/

Goodwin, Suzanne (NIH/OD)

From: Beth Pletcher [pletchba@umdnj.edu]
Sent: Tuesday, April 05, 2005 9:41 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Draft Document

I read with great interest the draft document on Coverage and Reimbursement for Genetic Tests and Services. It it quite comprehensive and timely. However, as a medical geneticist I found myself searching in vain for a clear niche for the clinical geneticist....especially in pages 1 through 48. What I failed to find was a delineation of the role of the medical geneticist, apart from any other health care professional or "provider" who is providing genetic information to patients. I clearly see the genetic counselors' roles in providing services that are apparently more cost effective than physician services. There is also the implication that because more genetic counselors are being trained than medical geneticists, the trend is for service provision by the genetic counselors rather than medical geneticists. What is completely absent is what is obvious to me: medical geneticists are not genetic counselors with a medical degree and non-geneticists are not exactly geneticists! Medical geneticists have traditionally worked in collaboration with genetic counselors in a team approach. While this model may become a thing of the past, medical geneticists are able to perform a physical examination looking for certain clinical features that genetic counselors are not trained to see, to review medical records that may require medical training for adequate interpretation, and to bring a breadth of clinical experience in dysmorphology and recognition of patterns of physical features that define specific syndromes to the table. The clinical findings for any given genetic condition are not something that can be printed out from an online resource and checked off when a patient is suspected to have a genetic condition, especially when the examiner has no background in genetic diagnosis. While I wholeheartedly agree that all medical professionals need to be educated about advances in genetics, to expect primary care physicians to provide in-depth genetic counseling and test interpretation for patients is frankly unrealistic. Perhaps the lack of a medical geneticist presence is partially attributable to our own uncertainty about our roles as medical geneticists now and in the future. With advances in enzyme replacement therapy and other therapies for genetic conditions, in the future, medical geneticists may play a role in therapeutics for genetic conditions. In summary, the failure to clarify what a medical geneticist is in this document (especially when we too provide genetic services that are very different from genetic counselors and other physicians) is, in my opinion, a serious oversight. Please consider adding a section that addresses the unique skill set defined by training in and the practice of medical genetics, as well as the need for medical geneticists to also be fairly reimbursed for their services. We too spend up to two hours with our patients and are not able to be reimbursed for our time. Evaluation by a medical geneticist may, in may cases, prove to be cost effective. Medically complex patients frequently see numerous specialists and subspecialists before landing in the genetic office. These patients often have had many costly tests including MRIs and molecular studies before a diagnosis is made by the geneticist. The medical geneticist may actually recommend a relatively small number of studies, or even make a syndromic diagnosis based on physical exam alone. Future medical care and preventative strategies can then be based on a specific syndromic diagnosis. Thank you in advance for your consideration of my concerns. By the way...page 76...the case is Safer v. Pack not Peck!
Sincerely, Beth A. Pletcher, MD, FAAP, FACMG

Reed V. Tuckson, M.D.
Chair, Secretary's Advisory Committee on
Genetics, Health and Society
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892

5/6/05

Dear Dr. Tuckson,

RE: Comments on draft report of Coverage and Reimbursement of Genetic Tests

I commend the work of the Coverage and Reimbursement Task Force and the SACGHS staff that resulted in this high quality report. The report covers all the major issues related to coverage and reimbursement of genetic tests in the U.S. I have the following comments:

1. Background:

i) Evidence-based coverage decisions (page 23): It may be useful to clarify that the typical process of evidence-based decision-making has two distinct phases: a) compiling the evidence through unbiased and systematic evidence collection and synthesis, and b) decision-making that often involves extrapolation and generalization of the evidence, weighing the harms and benefits, and making value judgments. Thus, decision-making is based on the evidence but is not confined to the evidence.

ii) Cost-containment and cost-effectiveness (pgs. 25-27): It may be useful to point out that the most crucial element of a good cost-effectiveness analysis is availability of good evidence of effectiveness. Additionally, the text does not clarify that cost-effectiveness, while important for societal decision-making, is not equivalent to cost-containment. Covering an increasing number of tests and interventions, even if all are cost-effective, is typically not compatible with the goal of containing costs, unless there is a commensurate reduction in coverage of previously-covered tests and interventions. Lastly, it may be useful to clarify that, when the U.S. Preventive Services Task Force (USPSTF) has reviewed cost-effectiveness studies, it has done so solely to inform its audience. At present, the USPSTF does not base its recommendations on the cost-effectiveness of a preventive service.

iii) Genotype-phenotype association (page 26): In defining genotype-phenotype association, perhaps the word "phenotypes" should be used instead of "outcomes". A genetic test that can detect or predict a phenotype (i.e., disease or disorder) with high sensitivity and specificity may be termed

clinically valid, even in the absence of its predicting clinical outcomes such as mortality or morbidity.

2. Recommendations:

i) Potential Recommendation on page 28: The word 'versus' in the text "...therapeutic versus informational benefit..." implies an either/or decision. It may be useful to acknowledge informational benefit as an important benefit, even if a group or body accords it lower value than a therapeutic benefit. By changing the text to "...therapeutic and informational benefit...", the committee would acknowledge that fact the decision-making group or body has taken into account both benefits and has not ignored informational benefit in favor of therapeutic benefit.

ii) Potential Recommendation on page 56: It may be useful to link the provider training and education tools with improved health outcomes of the patient. Evidence that appropriate provider training results in improved patient health outcomes is often weak. The evidence base can be greatly improved if more studies are funded in this area and the committee may want to consider explicitly recommending such research.

iii) Potential Recommendation on page 57: While it is important to disseminate information, there is also a need to disseminate information through a vehicle that will lead to better decision-making. There is not much evidence that having more information available on websites is the best way of communicating information to the public. The committee may want to consider recommending research on identifying the best means of communicating this information such that the consumer makes informed decisions on genetic testing. An on-going program that assesses the effectiveness of communication messages and improves the messages based on the assessment will be a valuable tool to educate the consumer.

Thank you for the opportunity to provide comment.

Sincerely,

Gurvaneet Randhawa, MD, MPH
Senior Service Fellow
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Goodwin, Suzanne (NIH/OD)

From: Elsa Reich [ereich64@yahoo.com]
Sent: Sunday, May 01, 2005 1:47 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: SACGHS report (draft)

I must commend the entire committee and other participants/contributors who developed such a comprehensive report for SACGHS which addresses some of the important issues arising from the genome initiative. This national effort is continuing to bear fruit for the individual consumer by way of the tremendous expansion of the applications of genetic medicine. The report accurately describes the comcomitant expansion of the applicability of genetic medicine and the decline in the number of professionals who are appropriately trained to provide these services. Part of this decline is due to the difficulty of supporting the services of these professionals via third party funding.

The education required by health care providers in genetics is extensive and complex. It is essential that professionals who are appropriately trained provide the necessary care to patients. Because genetic counseling is a relatively new profession, the standards upon which their qualifications are based are also relatively new. While state licensure may eventually provide national recognition of these standards, only three states have actually passed licensure laws. All three of these states have legislated that the state license is based on certification by the American Board of Genetic Counseling or by the American Board of Medical Genetics. These two Boards have correctly recognized the importance of a broad base of knowledge and clinical training as the measure of the competent genetic counselor.

Just as other medical professions develop standards for competency for their practicioners, so do genetic counselors. Currently through the American Board of Genetic Cousneling, these competencies are continually reviewed, revised and updated to conform with the rapid growth of genetic knowledge. I believe that it is essential that any report from SACGHS that addresses the issues of reimbursement for genetic services should include the recommendation that any genetic counselor qualifying for reimbursement should be a certified diplomate of the American Board of Genetic Counseling or the Ameircan Board of Medical Genetics. We must not only be concerned about reimbursement for genetic services, which is essential, but we must also assure that the individuals providing these services meet the highest standards. Those standards are embodied in the certification process developed by the American Board of Genetic Counseling.

Elsa Reich, MS, CGC
Professor of Pediatrics
New York University School of Medicine
Current board member, American Board of Genetic Counseling

Elsa Reich
4 Cummings Circles
West Orange, New Jersey 07052
973-736-1614
email at work: elsa.reich@med.nyu.edu

Goodwin, Suzanne (NIH/OD)

From: Thereasa A. Rich [thereasa@umich.edu]
Sent: Friday, April 29, 2005 7:09 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: SACGHS Public Comment

Dear Ms. Goodwin,

Genetic counselors are an integral part of the genetic medical professional team. They are specially trained professionals offering unique and important services to patients. They provide valuable information on the nature of genetic disease and genetic testing. They serve as an advocate, support system, and resource for their patients. Genetic counselors often spend an hour or more exploring complex scientific and psychosocial issues with many types of patients with differing backgrounds and sophistication. Their services should not be summed up by a physician's 10 minute check-in. Counselors should be able to bill for the appropriate complexity their time with patients earned. Further, a counselor's ability to bill will aid the clinic financially.

Thank you for considering this very important issue.
Thereasa Rich

Dear Ms. Goodwin:

I am writing in regards to the SACGHS recommendations on coverage and reimbursement for genetic counseling services. I believe it is essential that the committee strongly support genetic counselors in their efforts to bill independently for consults. It is not only critical for the survival of the genetic counseling field, but is necessary for ensuring quality genetic services in our communities.

I am a certified genetic counselor living in an area where there is typically a long wait for genetic counseling services. Two years ago, I opened a private genetic-counseling practice. My clients were mainly people who had questions about family history, infertility, or genetic testing. Although physicians expressed support for what I was trying to do, they did not refer many people. They indicated a reluctance to refer because their patients would have to pay out-of-pocket for the consults. Eventually, I closed the practice, but continued to get calls from area clinicians needing help with cases. Regrettably, I had to refer them to other providers, who were either backlogged or in another city.

One of the local obstetricians had suggested that I see patients in his office and that he would bill for the sessions and reimburse me. His office manager related that the Medical Society told him he would not be able to bill for genetic counseling unless he was a geneticist, and asked me what to do. Although there are non-geneticists billing for genetic counseling in this area, I did not want to create problems for his practice and declined his offer to work together. Until there is a clearly acceptable mechanism for billing for genetic counseling, patients will not get the genetic counseling services they need and the doctors are not going to get the help from genetic counselors they would like.

If genetic counselors continue to be unable to bill for services, it is inevitable that other professionals, who may not have had training in genetics, will be doing "genetic counseling" while certified genetic counselors are looking for alternative employment.

A local physician, who specializes in "longevity treatments," was offering "genetic counseling services" along with Botox injections, etc. When I asked him about his training in genetics, he said that a lab had come by one afternoon and taught him about cancer genetics. He couldn't recall which lab it was or, even, which cancers they told him about ("breast and uterine"? "breast and ovarian"?). Apparently, it did not matter.

Social workers are educating themselves on becoming "genetic counselors." While I appreciate their willingness to change and grow, I cringe when I think about this, as most social workers I know do not even have basic training in biology, much less genetics.

Years ago, while I was working at a local institution as a cytogenetics technologist, a social worker was hired to provide "genetic counseling." She had no idea how to interpret karyotype results. When an amniotic fluid sample revealed tetraploidy, for example, she wanted to counsel the parents on conjoined twinning. To her credit, she soon realized she was inadequately prepared for the job and resigned.

I believe that your decision regarding whether or not to support genetic counselors in their efforts to bill independently will determine the fate of genetics in society. If you support genetic counselors in this effort, so they have a means for earning a salary, they will be available to guide society into the genomics era. With their training in psychology, advanced genetics, and ethics, and their dedication to ensuring that genetic information is not misinterpreted or misused, they are perfectly qualified for this role.

If, on the other hand, you do not support genetic counselors in this effort, they will continue to leave the field for occupations where they can get paid. In the time it will take for substitute professionals to understand genetics, ignorant practitioners and opportunists will step in to fill the gap. If that happens, we

can be sure that there will be a transition period marked by ignorance, misinterpretation of information, and ethical abuses.

It took a long time for society to forget the cruelty of the eugenics era and to lose its bitter distaste for genetics. Master's-trained genetic counselors, more than any other group, helped to change those negative connotations by providing non-directive counseling, supporting patient autonomy, and striving to provide accurate and balanced information free from bias. If genetic counselors are not supported, and there are even *fewer* qualified genetics professionals than there are now, quality, compassion, and ethical considerations will be forsaken. The result may be a field that is permanently censured.

Please consider your decisions carefully. Not only will they influence the fate of the genetic counseling field, but they will also determine the future of genetics and its role in society.

Kathleen C Rossello, MS, CGC
Ph: 315.446.9421
kathleen.rossello@verizon.net

-----Original Message-----
From: Rowley, Peter [mailto:Peter_Rowley@URMC.Rochester.edu]
Sent: Friday, April 15, 2005 5:07 PM
To: SACGHS
Subject: RE: SACGHS Request for Public Comment

Secretary's Advisory Committee on Genetics, Health, and Society
c/o Ms. Suzanne Goodwin

Dear Committee Members,

Thank you for the opportunity to comment on the report "Coverage and Reimbursement of Genetic Tests and Services"

Two points deserve additional emphasis:

First, genetic tests are intended to predict future health problems so that they can be averted (e.g. in instituting intensive surveillance for cancer for those at high genetic risk). The requirement that the patient be already symptomatic before a genetic test can be paid for (e.g. by Medicare) undercuts the principal advantage of genetic testing. The presumed reason for not covering screening is the low yield. Yet the yield in families with a dominant condition is 50%, so this reason not to cover screening is fallacious.

Second, a test which makes the diagnosis of a genetic disease identifies a whole family at risk. This multiplier effect of genetic testing should receive greater emphasis.

If you issue another report, I have two suggestions:

First,. include a summary.

Second, avoid using white printing on a gray background; all the "recommendations" were very difficult to read for this reason.

Sincerely yours,

Peter T. Rowley, M.D.
Professor of Medicine, Pediatrics, Genetics, and Oncology
University of Rochester School of Medicine
Rochester, NY 14642

EVANSTON NORTHWESTERN HEALTHCARE

Evanston Hospital

The Center for Medical Genetics
1000 Central Street
Suite 620
Evanston, IL 60201

(847) 570-1029
(847) 733-5318 fax

April 28, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin:

As Medical Director of the Center for Medical Genetics at Evanston Northwestern Healthcare, I am writing in support of the Committee's recommendations to Congress, especially #7, regarding genetic counseling services and reimbursement issues. I would, however, like to see a strengthening of some of the key issues.

Our Center employs three ABGC-Certified Genetic Counselors in a clinical capacity and these counselors see approximately 60 appointments per month for conditions that affect adults. Five additional counselors are employed by the Department of Obstetrics-Gynecology. With the preparation time, counseling sessions, blood draws, disclosures and post-visit evaluations, having non-physician National Provider identifiers assigned to our Certified Genetic Counselors with the ability to bill independently is an urgent need. It would certainly increase access to our services if our counselors had the capability of billing independently of the physicians. At present the counselors need to supplement their positions with research studies to cover their salaries. Having the capability of billing would open the schedule to more appointments which would serve those in need of genetic counseling in a timelier manner.

Frankly speaking, our program and others around the country typically rely on the good graces of hospital administrators to absorb the uncovered costs of genetic counselors. In the current financial climate, this translates into very poor access for most patients because a genetic counselor cannot be employed in their community. This also puts existing programs such at ours at high risk of cutbacks. It is clear that overall demand for genetic services is high, that most physicians lack sufficient training and time to fill this need, and therefore that this need is unmet. Given that genetic counselors have the most rigorous training in the science and psychology of genetic counseling, it is absolutely essential that we support their specialty by making it feasible for them to survive as a profession. Indeed, the vacuum created by the lack of reimbursement mechanisms for genetic counseling services has begun to create a totally unregulated market for what is termed "genetic counseling" but clearly is not according to professional standards. I would therefore further advise that additional studies be done to assess other professionals who may not currently have as robust credentialing programs as do genetic counselors.

The state of Illinois has taken the first step in approving the licensing of genetic counselors and our counselors are ABGC certified. With these credentials I would like to request that the recommendations include a provision that these certified counselors should be considered as qualified providers with the ability to bill independently.

Thank you in advance for reading my comments.

Sincerely,

Wendy S. Rubinstein, MD, PhD, FACMG
Medical Director, Center for Medical Genetics
Evanston Northwestern Healthcare
Assistant Professor of Medicine
Northwestern University Feinberg School of Medicine

Goodwin, Suzanne (NIH/OD)

From: jodirucquoi [jodirucquoi@cshore.com]
Sent: Wednesday, April 27, 2005 6:05 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Genetic counseling

Ms. Goodwin:

I urge you to support genetic testing and coverage for genetic counseling. Now that we at last have excellent and reliable tools with which to detect both carriers and those affected with genetic disorders, the patients must be given accurate and sensitive counseling in order to understand the complexities involved.

We have board certified genetic counselors who are trained in genetics and counseling to provide this service and they must be reimbursed appropriately. While it would be reasonable to hope that primary care physicians could provide this patient care, it is currently beyond their expertise and time constraints.

The technology is here, we must be prepared to implement patient care.

Please support this important effort.
Thank you.

Jodi K. Rucquoi, MS ABMG
Certified Genetic Counselor

Goodwin, Suzanne (NIH/OD)

From: Marc G. Rucquoi, M.D. [mrucquoi@thefhc.com]
Sent: Tuesday, April 26, 2005 7:04 PM
To: Goodwin, Suzanne (NIH/OD)

As a family physician in South Carolina, I am emailing you to voice my support of **coverage and reimbursement** of genetic tests and services (genetic counseling). This should be put into effect now since there are health professionals certified and qualified to provide these services -- as well as (and most importantly) patients who would benefit from these services.

Thank you for your time and consideration.

Marc Rucquoi, MD

++

"A joyful heart is good medicine" Proverbs 17:22

Marc G. Rucquoi, MD
The Family Healthcare Center, P.A.
23013 Highway 76 East
Clinton, South Carolina 29325
864.833.5986

Goodwin, Suzanne (NIH/OD)

From: Santi-Bauer, Andreina [asanti@svcmcny.org]
Sent: Monday, May 02, 2005 3:10 PM
To: Goodwin, Suzanne (NIH/OD)

Dear Ms. Goodwin:

I have reviewed the SACGHS report regarding genetic counseling services and would like to commend you and the committee on your hard work and thoughtful commentary.

As the Administrative Director of Pediatrics and OB/Gyn at a major urban medical center, who is responsible for overseeing billing and reimbursement of genetic counseling services, I feel strongly that the document would be improved if it included a specific recommendation to add genetic counselors to the list of health care professionals who are eligible to bill Medicaid and Medicare as independent providers. We value the services that genetic counselors provide at our institution, but financial pressures make it a difficult program to justify. Improving the direct billing prospects would be of great benefit to the institution and to the patients we serve.

Thank you for your consideration,

Goodwin, Suzanne (NIH/OD)

From: Angela Scheuerle [ascheuerle@swbell.net]
Sent: Wednesday, April 06, 2005 12:07 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comments on Genetic Reimb WkGrp

Good morning,

Re: Draft Report on Coverage and Reimbursement of Genetic Tests and Services.

I am a Clinical Geneticist in private practice and do not have the advantage of being able to use institutional billing for genetic laboratory services. The problems outlined in the draft report are all important. I have comments on two specific issues:

1) It is mentioned that some genetic service laboratories do not contract with insurance companies. This is true and is a significant hindrance in the private practice setting. Additionally, an up-front payment of 50-75% of the cost is required. A Clinical Geneticist based in a medical school or other large program may be able to defer to institutional billing. A solo private practice cannot maintain the capital to cover up-front laboratory fees. Even in such an instance, the cost would be transferred to the patient, who will be billed by the private physician, probably at a loss.

Alternatively, the burden is shifted to the patient who is required either to pay out of pocket or to obtain confirmation from the insurance company that a test will be covered. This may be irrelevant for a test costing less than $100, but some tests cost over $2000, which is prohibitive. Some insurance providers either do not provide such letters or refuse coverage. If coverage is provided, it can require significant time and effort on the part of the patient and/or physician to obtain it. Obviously there is no reimbursement for physician time spent in discussion with the insurance company.

For newer and more "esoteric" tests, (i.e., not karyotypes) it has become my practice to include a discussion of test cost in counseling a family about testing and to discourage testing unless there is a specific treatment or immediate recurrence question to be answered. I am hopeful that advancing technology will lead to faster, cheaper testing in the relatively near future. Since most of my patients are infants and young children I can reasonably suggest deferring tests until, say, school age, puberty, or a generational time of reproductive decision making.

SUGGESTION: In addition to an objective evaluation of test usefulness, it would be very helpful if laboratories offering genetic testing be required to contract with (or have some other relation) to insurance companies. This would increase availability of testing to patients. Perhaps a compromise that testing meeting certain requirements would be billed to insurance and newer, more "experimental" or less sensitive/specific testing would require self-pay or insurance company petition.

2) A problem that is implied but not specifically stated is that some insurance companies will cover a Clinical Genetics clinic visit, but will not pay for any genetic testing. This is policy-dependent. I have found in practice that it has caused some patients to refuse consultation all together. I have explained it occasionally as agreeing to pay for the cardiologist, but not for the ECHO.

SUGGESTION: If insurance companies are reluctant to pay for genetic

testing across the board, require them to pay for testing ordered by a Clinical Geneticist. Conversely, coverage of testing could be increased if ordered by a genetic specialist rather than another physician. This would decrease the penalty for those communities without a geneticist and would encourage involvement of a clinical geneticist in patient care.

Thank you,

Angela Scheuerle, M.D.

--
Angela Scheuerle, M.D.
Genetics, Teratology, Ethics
7777 Forest Lane, C706
Dallas TX 75230
Ph 972 566 6524
Fax 972 566 4624
ascheuerle@swbell.net

Goodwin, Suzanne (NIH/OD)

From: BARBARU@aol.com
Sent: Monday, March 28, 2005 3:10 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: public comment

While there is a great disparity in what will be covered by various private health insurers and Medicare, until I read this, I did not know that coverage under Medicare varied according to what part of the country one lived. THIS IS NOT FAIR! This inequality must be evened out. Medicare is a NATIONAL program and as such must be national in scope and coverage.

If the US government orders every state's Medicaid program to cover any specific procedure, it must be prepared to pay the state to cover the procedure. I find inequities in coverage from state to state to be unfair

As for private insurers covering or not covering any procedure, it could be put into practice that every insurer must offer coverage, but perhaps not under every plan it offers.

Thank you for your concern.

Barbara R. Seidman
24 Foxtail Lane
Monmouth Junction, NJ 08852-2006
(732) 274-0850
fax: (732) 274-0960
barbaru@aol.com

Co-Coordinator: NJ chapter PKD Foundation for Research in Polycystic Kidney Disease
Member: American Association of Kidney Patients
Member: Transplant Recipients International

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER℠

MASSACHUSETTS
GENERAL HOSPITAL

Kristen Mahoney Shannon, MS, CGC
Senior Genetic Counselor

Center for Cancer Risk Analysis
55 Fruit St. – YAW 9
Boston, MA 02114-2617

Tel: 617 724-1971, Fax: 617 726-9418

April 25, 2005

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Dear Ms. Goodwin:

I am writing to comment on the draft recommendations regarding coverage and reimbursement that the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) has recently published. I am writing as Senior Genetic Counselor working at Massachusetts General Hospital Cancer Center. Our center has three genetic counselors staffing the Cancer Genetics program, where we see approximately 1200 patients per year for cancer genetic counseling.

I would first like to commend the SACGHS for an excellent report. I also understand that although the Secretary cannot influence legislation, the group's comments are taken into account by other funding decision-makers. Thus, I am specifically responding to "Recommendation #7", regarding genetic counseling services and reimbursement issues.

As you know, access to genetic counseling services is of the utmost importance. Currently, there is limited access to these services for various reasons: one of which is that genetic services are not currently 'billable services'. Genetic counselors are not providers that are recognized by CMS, which makes their services non-billable. This is a major stumbling block and prevents many individuals from seeking and obtaining genetic counseling services, which in many cases are necessary for both individual and public health reasons. *Thus, I specifically request that the recommendations to the Secretary include ABGC certified genetic counselors as qualified providers who should have the ability to bill independently.*

Again, I would like to comment the SACGHS on their efforts. I wholeheartedly support the remainder of the recommendations regarding genetic counseling service coverage and reimbursement, including the reimbursement of prolonged service codes both for direct and incident to billing. I also support the inclusion of non-physician health care providers eligible to directly bill health plans as eligible for national provider identifier (which will replace UPINs).

Thank you for the opportunity to comment on these recommendations, and I look forward to reading them in their final form.

Sincerely,

Kristen Mahoney Shannon, MS, CGC
Senior Genetic Counselor

Goodwin, Suzanne (NIH/OD)

From: hshappell@lifemapgenetics.com
Sent: Tuesday, May 03, 2005 12:26 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: factual error on page 29

Dear Ms Goodwin,

There is a factual error on page 29.

Coverage for BRCA1/2 genetic tests is NOT different depending on where a beneficiary lives themselves but, on where the test is sent. The local BRCA1/2 coverage policy of Medicare (Regence BC/BS of Utah) covers the laboratory test when it is sent to Myriad Genetics which is the only laboratory in the US who can legally perfomr BRCA testing. A more serious issue is that HNPCC related tests (MLH1, MSH2, MSH6) are only covered when sent to Myriad as well although there are a number of other laboratories who provide testing for these genes.

So, HCP's laboratory options are severely limited when the policy is made on a local basis rather than a national basis.

I'm happy to speak with you about this in more detail. I actually worked at Myriad Genetics and worked with the local Medicare Medical Director to develop their current coverage criteria.

Sincerely,
Heather L. Shappell MS, CGC
Licensed Genetic Counselor
Director of Genetic Consulting, Co-Founder
LifeMap Genetics, Inc.
1.801.571.0082
www.lifemapgenetics.com

Goodwin, Suzanne (NIH/OD)

From: Celette Sugg Skinner [skinn008@mc.duke.edu]
Sent: Friday, May 06, 2005 9:19 AM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comment on recommendation

Dear Dr. Goodwin,

I am a faculty member in the Duke Comprehensive Cancer Center's Research Progrma in Cancer Prevention, Detection and Control and I am writing to commend the Secretary's Advisory Committee on Genetics, Health and Society's recommendations on coverage and reimbursement of genetic testing and genetic services. This will be a very positive change and should result in provision of this important service of genetic counseling to many more individuals who will benefit from it. I do believe, however, that one change is essential in this recommendation. My experience researching communication of risk information and genetic testing decision making indicates that unique training is necessary for counseling people about the complex genetic, medical and psychosocial issues involved in genetic testing. Therefore, it will be important to amend recommendation # 7 (page 52) to limit billing privileges to ABCS-certified genetic counselors -- not any provider who fancies him or herself to have specialized expertise in genetics.

Thank you.

Celette Sugg Skinner, Ph.D.
Associate Professor, Departments of Surgery and Community & Family Medicine
Duke University Medical Center
Member, Research Program in Cancer Prevention, Detection and Control
Duke Comprehensive Cancer Center
(919) 684-4791
Celette.Skinner@Duke.edu

Goodwin, Suzanne (NIH/OD)

From: TeachEco@aol.com
Sent: Monday, May 02, 2005 10:28 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Comments on Recommendation

Please find attached comments made on the recommendations in the Secretary"s Advisory Committee on Genetics, Health, and Society. This was actually done as our final exam in a Human Genetics Course.

SACGHS Recommendations

Potential Recommendation #1
I agree that there is a need to establish such a committee to meet the needs of the general public regarding genetic testing and insurance coverage. The group members should include knowledgeable individuals in the area of genetics, doctors, genetic counselors, health insurance representatives, members of SACGHS as well as from other public and private sectors. Once established, the committee should examine each type of genetic test presently available to determine, as suggested in the recommendation, the various issues, such as analytical and clinical validity, prevention, therapeutic and informational benefits. Once the above information has been studied, the committee would be able to determine which genetic tests should be covered without question, under all circumstances. The remainder of the tests should be considered as a separate group, not two to be broken into "not covered " and "maybe we'll see". This second group should be covered under certain circumstances, but not all. It would have to be determined by the doctor/doctors, in determining what is in the best interest of the health of the patient, genetic counselor, and the insurance carrier. There would be a need for some kind of checklist that would be helpful in determining the importance of testing under these circumstances.

A subcommittee could be established to study all new information that they receive concerning new genetic tests that become available. They would also be responsible for gathering additional data/evidence on existing genetic tests. As technology improves, periodic adjustments to coverage may be needed to account for these advances. Any new information should then be made available to health insurance carriers. Such a review may be needed every 2 to 5 years.

Potential Recommendation # 2
I agree with this recommendation. "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 population they serve". As suggested in #1, these types of tests should be included in group one, those tests covered under all circumstances. When testing is done very early on, knowing what to expect and what can be done to decrease or eliminate the disorder, would lower the costs to insurers and payers in the long run. Many genetic disorders can be very expensive once they manifest themselves. If something can be done to prevent or lessen the effect of the disorder, it will require less money over time.

Potential Recommendation #3
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"is very important. These evaluations need to be done on a continual basis at the local level before going to the national level. Because genetic technologies are constantly changing and improving, coverage of various genetic tests need to be constantly updated. Consistency across the board, and not limited to certain areas, would guarantee that there would be less variations in coverages. This would help to eliminate any inequity in the system.

Potential Recommendation #4
I agree with this recommendation. If an individual does not show symptoms or family history, there is an advantage to being tested. There could be other "circumstances and where scientific evidence warrants" that would indicate that testing would predict a predisposition/no predisposition for certain genetic disorders in the future. This could have a major influence on what this individual may or may not need in terms of insurance. There would again be a need to determine ahead of time, what types of tests should be carried out and covered by Medicare and/or local carriers. Genetic counseling should be included in this coverage, if not by Medicare then by local insurance. Genetic counseling could/should be able to determine if testing would be "reasonable and necessary". This would give individuals more information concerning not only what the genetic tests could show but what will possibly need to be done, pending the outcome of the tests. Individuals would be able to make more informative choices. This would benefit both Medicare and local insurance carriers. The information received from these tests if predisposition is shown, might also benefit other members of this individual's family. The same would then apply to them as far as preventive testing. This could be very cost-effective in the long run. Again, preventive testing would benefit everyone.

Potential Recommendation #5
The Secretary should be responsible for making sure that all state agencies and issuance carriers are informed of the "existing evidence base and other supporting information" concerning genetic tests. It seems that the states should be more uniform as to what they will cover and what Medicaid would cover. State coverage should not be based on political views, which are often based on personal opinion rather than on what would be in the best interest of the health and well-being of the constituents. If budgets require cutbacks in Medicaid benefits, it might be advantageous to do so on a case by case basis. What might truly be required for one individual may not be so true for another at the same time. Again, having genetic counselors available would benefit everyone. Preventive testing would be cost-effective as well. States need to figure out a way to keep services in balance without having to drop certain tests or neglect certain portions of the population. If HHS continues to support states, with grants, and encourage them in using those accepted tests, then having a healthy population will also help to keep state budgets healthy.

Potential Recommendation #6
I agree that there needs to be an appropriate fee schedule for the costs of genetic testing and what is involved in those tests. If the fee schedule that exists in its present form, until 2009, is not appropriate for all genetic tests codes, then "inherent reasonableness" will play a very important role in correcting those payments that could be considered "grossly excessive or deficient". As genetic technologies improve, the cost for genetic tests and services, hopefully, will be lower and will fit more appropriately into the present fee schedule. Finding newer and less expensive testing and related services will help to reduce costs to make those tests more "reasonable". The more costly older tests and the newer less expensive tests will eventually balance themselves out. "Inherent reasonableness", at the present time, will require constant evaluation until the "fee freeze" has ended.

Potential Recommendation #7
I agree that "genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services". In the first part of this recommendation, anyone providing genetic counseling, be it a health provider or other party, they should be able to bill directly for their counseling. There does need to be a list of what/who constitutes a qualified genetic counselor. All individuals having that title or acting as one should all be subject to the same licensing and credentials across the board, state to state. This would guarantee that these genetic counselors would "ensure quality and safety of health services". This would then allow all those health providers who are considered genetic counselors to bill directly. This would allow for less paperwork, fewer mistakes and allow these individuals to be reimbursed sooner.

I also agree that there should be reimbursement for prolonged/extended service. The time factor should be included in the coding for billing of services. For those codes that involve a time period, for example - code 99201-99205 for Office/outpatient service - new patient self-referred, 10-60 minutes, perhaps the actual minutes involved should be included in that code. Because these codes are used in other areas of health services, a code used strictly for genetic counseling should be considered.

Potential Recommendation #8
I concur completely with this recommendation. Because today's technologies are constantly changing, ongoing training and continued education becomes extremely important. If health care providers do not keep up with current data/evidence in genetics and genomics, understanding what their plan members need will cause a lapse in important coverages. It would help the providers to make sure that the plans they offer will continue to help those in need of it. It would also allow the providers to present new information to their clients. It allows for both provider and client to make better decisions about their health care. It should be the duty of HHS to provide the "development, cataloguing, and dissemination of case studies and practice models that demonstrate the current relevance". This would provide the same information, data, evidence to all providers allowing each to do a better job. Genetics and genomics are changing at a very fast rate and health care providers need to keep up with those changes.

Potential Recommendation #9
This is a good recommendation as long as it does what it presently says. Many people would argue that they do not want to have their personal genetic history available on the Internet. The fear that this information will somehow be used against them is a very big issue. It could violate a person's right to privacy, cause them to lose a job or even health insurance if gotten into the wrong hands. Personally I would worry about the information that I found available. How can I be sure that this information is "reliable and trustworthy"? If all the information about family histories and genetic testing results can be anonymous, perhaps more people would feel safer about having this type of information being made available online. If names are included, this will not work well. Individuals will be leery of giving this information to anyone, licensed or not. Information concerning genetic testing and genetic advances in technologies would be very beneficial. These types of information could be very helpful for those looking to see what might be their best course of action for their particular genetic reason, as long as it can be guaranteed accurate.

Goodwin, Suzanne (NIH/OD)

From: Troxell, Robin M. [troxellr@health.missouri.edu]
Sent: Monday, May 02, 2005 12:44 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: comments on the draft report "The Coverage and Reimbursement of Genetic Tests and Services"

Dear Ms. Goodwin:

I am writing to provide my comments on "The Coverage and Reimbursement of Genetic Tests and Services" put forth by the SACGHS. I am a genetic counselor certified by the American Board of Genetic Counseling. I have five years of experience, and currently work for a university medical center and a private hospital. I appreciate the hard work your committee has put into the issue of genetic testing and genetic services. I would ask that you emphasize the importance of ABGC certified counselors being able to bill. In my state (Missouri) we are not recognized as providers and thus provide all of our services for free. Since our state budget for 2004 was reduced last month, and cut nearly in half for 2005, the availability of genetic services is in great peril. The ability to obtain a national provider/UPIN number and to bill would help in justifying and solidifying our positions as appropriately trained health care professionals.

I also applaud your efforts to increase reimbursement for genetic testing. Since 2/3's of our patients have Medicaid, our hospital absorbs hundreds of thousands of dollars worth of testing that is not reimbursed, but we cannot bill the patients for either. This situation cannot continue.

Thank you for your time and consideration.

Robin Troxell, MS, CGC
Certified Genetic Counselor
University of Missouri
Mercy St. John's Health Care Systems

The University of Michigan
Molecular Medicine and Genetics
Ann Arbor, Michigan 48109-0638

Molecular Medicine and Genetics

4301 MSRB III, Box 0638
Internal Medicine
Ann Arbor, MI 48109
(734) 763-2532
(734) 763-7672 (FAX)

May 6, 2005

Dear Members of the Secretary's Advisory Committee on Genetics, Health and Society:

We commend the SACGHS for addressing the critical issues of coverage and reimbursement of genetic tests and services and ranking these as high priority issues. As genetic counselors, geneticists, clinic coordinators and administrators, we can attest to the fact that problems with insurance coverage and reimbursement are limiting patients' access to genetic tests and services. It used to be that patients obtained a second opinion from a physician; now second opinions and even first opinions are being rendered by insurance companies – "opinions" that can mean patients do not get access to clinically indicated genetic services.

We present feedback on the report and share experiences from our Medical Genetics and Cancer Genetics Clinics that raise some additional billing and reimbursement issues not addressed in your excellent report.

In our clinic, problems with insurance coverage have resulted in:

- **an increase in patients canceling appointments because insurance will not cover the costs of the clinic visit**
- **an increase in calls from patients wanting to know the CPT codes that will be used for the visit, which can be difficult to provide when you have not yet seen the patient and have limited medical or family history information**
- **incomplete genetics evaluations, which limit our ability to establish or confirm a genetic diagnosis, because insurance will not cover the costs of genetic testing**
- **an increase in the amount of time we are spending addressing insurance issues with our patients at the time the appointment is scheduled and during the clinic visit**

- **an increase in the amount of time we are spending calling and writing letters to insurance companies requesting coverage for genetic services**

- **an increase in the number of patients having to return to our clinic a second time just to have a blood draw for genetic testing because insurance coverage of genetic testing could not be obtained at the initial clinic visit**

In our clinic, we have had insurers:

- **deny payment for genetic testing for conditions with significant morbidity and mortality, where diagnosis would affect surveillance and management**

- **deny payment even when the genetic test would be less costly than other tests**

- **deny payment for genetic testing that would benefit not only our patient's care but the care of other family members as well**

At the time the patient is seen in clinic and genetic testing is recommended, it is often difficult to obtain from insurers immediate approval to proceed with genetic testing. Insurers can easily determine whether an MRI or CT scan will be a covered benefit but coverage of genetic testing may not even be specified or clearly delineated. It is not unusual for us to have to write letters justifying the need for genetic testing. Even then, some insurers will not give a definitive answer about coverage and will just indicate that it would be "reviewable," which potentially leaves the patient liable for the full cost.

It decreases our clinic efficiency and means other patients have to wait longer to be seen when we have to see patients back a second time to order genetic testing that could have been done at their initial visit if it wasn't for insurance coverage issues. For our patients, it can also mean a several hour drive to our clinic and having to take additional time off from work, just for a few minutes blood draw.

The time we spend discussing insurance issues with our patients and addressing these issues with their insurers is valuable time that could be spent providing genetic services. Additionally, when patients have to jump through several hoops with their insurance for coverage of genetic services, this only makes the service seem less a part of standard medical care and can lead to greater anxiety about insurance implications and potential risk for

discrimination. If genetic services were covered just like other medical services, this could lessen patients' fear of genetic discrimination.

A recent case from our clinic which is typical of the insurance issues that we face:

A patient with aortic root enlargement was referred for evaluation for Marfan syndrome, results which would have implications for surgical intervention and healthcare. He had mild musculoskeletal features, but did not have sufficient clinical features to make a definitive diagnosis of Marfan syndrome. We recommended genetic testing because mutations in the fibrillin gene have been identified, even in patients who do not have classic clinical features of Marfan syndrome. Our request for coverage of genetic testing by his insurance company was denied, despite a strong letter documenting medical necessity. We have had several other cases where insurers denied coverage for genetic testing for Marfan syndrome. Reasons for denial include "not a covered benefit" and "testing is considered investigational." Given the diagnostic implications, our patient used savings to pay for the $2000+ test. A fibrillin mutation was identified, supporting a diagnosis of Marfan syndrome. Establishing a diagnosis meant that informed decisions could be made for his healthcare and that he could receive appropriate care and surveillance. Given that Marfan syndrome is an autosomal dominant condition, identifying the fibrillin mutation also enables cost-effective testing (~ $300 - $500) of his first-degree relatives and the medical system can be spared the cost of annual echocardiograms for decades for family members who test negative for the mutation.

Current Insurance Approval Challenges

Patients generally cannot just call their insurance company to ask if genetic testing for Marfan syndrome is a covered benefit. Insurers want to know the CPT codes. Therefore, we are either put in the position of spending time on the phone (usually a long-distance call) discussing with patients that genetic testing may be recommended and these are the codes that would be needed – time wasted if the patient does not show for their appointment or our clinical evaluation yields a different diagnosis. Many insurers want a letter of medical necessity before they will even make a determination about covering the genetic testing fees. To write such a letter, one generally needs to evaluate the patient first. Therefore, to have the patient call their insurer prior to their appointment is generally of limited use.

It takes time to provide patients and/or insurers with the CPT codes because there are multiple CPT codes for each genetic test, each code specific for a step in the genetic testing process. There is clearly a great chance for errors to occur when patients record this information, given that the 5-digit numbers are similar and easily transposed.

For example – Genetic Testing for Marfan syndrome:
Fibrillin Full Mutation Analysis: 83890(x2), 83898(x43), 83894(x43), 83904(x43), 83912

We've had insurers say they will cover some of these codes, but not others! These codes all correspond to steps in the genetic testing process and cannot be individually selected. Particularly, we've had insurers state that they would deny coverage for code "83912" which is the interpretation of the test results. We have explained that the laboratory has to interpret the LABORATORY results (e.g. what they saw on their gel) and that is distinct from the physician then interpreting the results CLINICALLY for the patient.

Even if CPT codes for a genetic test are covered by the insurance policy, reimbursement may be significantly lower than the actual charges. We support your recommendation on page 45 of the report "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 CPT codes through its inherent reasonableness authority."

Billing Issues

It is not unusual for laboratories to charge different fees for the same genetic test depending on whether insurance, the institution or the patient is billed.

Example: Genetic Testing for Marfan syndrome
- If patient is fully paying out of pocket for testing: 15% off insurance price

Fibrillin Full Mutation Analysis
Insurance billed: $3667.97
Institution billed: $1975.00

Known fibrillin mutation:
Insurance billed: $510.17
Institution pricing $300

This can present a quandary, given current billing practices. With these differential pricings, the billing decision can boil down to who should take the financial hit - the patient or the institution? It is in the best interest of the patient to be billed the least amount for the test, which as you can see above would be the fee for institution billing. The institution however would prefer to have the patient's insurance billed directly for the test – that way, they are not financially in the loop. If the institution pays for the test, then bills the patient's insurance, they stand to lose money if the insurance doesn't pay and the patient is not billed or does not pay the remaining costs. If the patient's insurance is billed, which in this case is $1693 more than what the institution would be

charged, the patient could be left paying several hundred dollars out of pocket if insurance does not cover the full amount. In fact, several laboratories will require the patient to pay 20% of the testing cost up front if insurance is billed. This can amount to several hundred dollars and be financially burdensome to patients to pay and contribute to limiting access to genetic services.

We encourage the SACGHS to address this differential test pricing issue and the implications for billing in your report.

Lack of Appropriate Billing Codes

Many genetic conditions are rare and do not have established ICD-9 codes. We may therefore be interrupted in seeing patients to help the billers come up with a code that can be used to charge for the clinic visit. Genetic conditions are often multi-systemic. Without specific ICD-9 codes for the genetic condition, we are left trying to identify a code that is tangentially related or find a code for a major symptom of the genetic condition. This can be both difficult and time-consuming.

In addition, many patients come to our clinic to rule out a genetic condition. They may not have the genetic condition so use of the diagnostic code for the genetic condition is not accurate. Use of "V codes" also do not accurately capture why the patient was seen and as you state on page 43 of the report "Health plans have sometimes been reluctant to reimburse V codes, and when they do, the reimbursement rate is often low." As in cases where there is not a specific ICD-9 code for the visit, we try to find a code for a symptom the patient has of the condition to be ruled out – for example, a patient seen to rule out Marfan syndrome may have joint hypermobility for which an ICD-9 code does exist.

Specific CPT codes have been proposed to the AMA CPT Editorial Panel for family history/risk assessment/pedigree analysis. These codes accurately reflect the components of genetic counseling. Adoption of these codes is needed to improve and accurately bill for genetic counseling services.

Reimbursement depends on accurate coding so it is important that the lack of appropriate billing codes be addressed. As you state on page 36 of the report "If existing coding systems are not sufficiently descriptive of the service being provided and the reason it is provided, it can be difficult for health insurance plans to process the claim appropriately and efficiently....If claims for genetic tests and services are repeatedly denied due to inadequate codes, providers and laboratories may become less willing to offer these tests and services or to accept third-party reimbursement." Without appropriate reimbursement, access to genetic services and testing will be limited to those who can financially afford it.

SACGHS Proposed Billing Recommendations

We enthusiastically support SACGHS' proposed recommendations on page 52 of the report regarding: qualified health providers directly billing for genetic counseling services; reimbursement of prolonged service codes; review of adequacy of existing CPT E & M codes with respect to genetic counseling services; use of full range of CPT E&M codes available for genetic counseling services by qualified non-physician practitioners; and extending eligibility for an NPI to all non-physician health providers. These actions would be important steps for addressing coverage and reimbursement for genetic services.

Recognize ABGC certified genetic counselors and GNCC genetic nurses

In the SACGHS report on page 52, ABGC certified genetic counselors and GNCC genetic nurses should specifically be listed as qualified non-physician health providers who are qualified to provide genetic counseling services and bill for these services. There could be greater access to genetic services if these qualified healthcare professionals were recognized as providers of these services. Without this recognition, the trained work force cannot be fully utilized, further limiting patients' access to needed genetic services.

Currently, the number of patients that can be scheduled in our genetics clinic (and other clinics across the country) is limited by the fact that all patients seen by a genetic counselor need to be staffed by a geneticist/physician. With few exceptions, genetic counselors cannot bill for their time with patients. Money is therefore lost by the medical system because patients typically are seen for an hour plus in genetics clinics, but only the physician face-to-face time can be billed. For genetic counseling cases where no physical exam is involved, the patient will receive an hour+ of healthcare but just be billed for 15 minutes or less - the physician face-to-face time. A great deal for patients, a break for their insurers and a loss for the medical system.

It should also be noted that often a significant amount of time is needed to prep a genetics case – time that is not billable. In order to provide accurate genetic counseling, it is standard to construct a 3-generation pedigree; obtain and review medical records; search the medical literature for up-to-date information about the genetic condition since there are a couple thousand different conditions and information is rapidly changing; determine if genetic testing is indicated and, if available, contact laboratories across the country to see what is offered; and locate appropriate educational resources and support groups for patients.

ABGC genetic counselors and GNCC genetic nurses have focused training in genetic counseling, meet stringent training requirements and take national

examinations. It would be a serious oversight of this report to not specifically list them as qualified non-physician health providers who are qualified to provide and bill for genetic counseling services.

Licensure may partially address billing issues but is not the answer because it will take years to achieve this. It has taken the American Association of Marriage and Family Therapy 30 years to obtain licensure in 42 states and over 20 years to obtain social work licensure in 48 states (Allain D 2004 *J Genet Counsel* 13:1-7). We do not have years to wait if we want to provide access to genetic services and enable patients to reap the benefits from genetic advances.

Involvement of Multiple Providers: On page 13 of the report, it is noted that one challenge is coordination of care and coverage and reimbursement of genetic services given that several healthcare providers may be needed in a patient's care. This is no different for patients needing genetic services than it is for patients needing care by any specialist. A patient being treated for cancer will likewise have several healthcare providers working with them, including their primary care physician, oncologist, radiation specialist, chemotherapy provider, surgeon and other supportive services.

Treat being at significant risk for a genetic condition as a coverable indication: Insurance coverage has particularly been a problem for patients who have a family history of a genetic condition but are asymptomatic and therefore are billed using "V" codes. Having a significant risk (e.g. 25% risk, 50% risk) for a genetic condition needs to be viewed by insurers on a similar par as having a symptom. In addition, with genetic advances, there is going to be increasing availability of predictive genetic tests – tests that will have benefits for healthcare. In order to realize these benefits, there needs to be insurance coverage of predictive tests. It is time to think of reclassifying tests for coverage purposes. Other less than perfect screening/risk assessment tests, such as PSA and lipid profiling, are covered by insurance and likewise genetic tests should be similarly covered. We heartily support your recommendation on page 32 "...that preventive services, including predispositional genetic tests and services, meeting evidence standards should be covered..." and "personal history may include family history of a particular disease for purposes of establishing that a genetic test is reasonable and necessary."

Genetic testing is a moving target: A CBC is a CBC, regardless of where it is performed and results are straightforward to interpret. It also can be simply ordered – just check off a box on a form. It is not unusual to have to spend 20+ minutes just to complete the paperwork to order a genetics test. Many genetic tests are "home brews" and what is offered by one laboratory can differ from another. In addition, accurate interpretation of genetic test results can encompass several variables including genotype-phenotype correlations,

penetrance and variable expressivity. The same genetic test can have multiple applications and different implications depending on the application. We can share several cases where genetic counselors and geneticists' expertise in laboratory selection made a crucial difference in making the diagnosis.

Professional Guidelines/Standards of Practice: On page 22 of the report, the SACGHS raises reasonable questions to consider in making coverage decisions for new technologies. Given that genetic testing is a moving target and the complexity involved, there should be greater reliance on having coverage of genetic tests dovetail professional guidelines and standards of practice.

We commend the SACGHS in putting together a thoughtful and informative report on coverage and reimbursement of genetic tests and services. As noted above, it will take a multi-pronged approach to address these critical issues. Genetic tests are becoming more a part of mainstream medicine in diagnosing diseases and assessing risk of disease. Therefore, they should be treated like other medical tests that are routinely covered and reimbursed. Recognition of qualified providers of genetic counseling and addressing these billing issues are critical. Unless these issues are successfully resolved, access to genetic services will be limited and only available to those who can afford it. Genetic advances have great potential to enhance our healthcare. We strongly support and encourage the SACGHS to address these critical issues so that the benefits to patients can be fully realized in a timely manner.

Sincerely, **

Wendy R. Uhlmann, MS, CGC
Genetic Counselor/Clinic Coordinator Medical Genetics Clinic, Division of Molecular Medicine and Genetics, Department of Internal Medicine; Clinical Instructor, Department of Human Genetics

Gilbert S. Omenn, M.D., Ph.D.
Professor of Internal Medicine, Human Genetics, and Public Health
Former CEO, University of Michigan Health System

Elizabeth M. Petty, MD
Associate Professor of Internal Medicine and Human Genetics; Service Chief, Division of Molecular Medicine and Genetics; Outpatient Clinic Director of the Medical Genetics Clinic

Thomas D. Gelehrter, MD
Professor of Internal Medicine and Human Genetics

David Ginsburg, MD
Professor of Internal Medicine and Human Genetics

Stephen B. Gruber, M.D., Ph.D., M.P.H.
Associate Professor of Internal Medicine, Epidemiology, and Human Genetics
Director, Cancer Genetics Clinic

Wendy Kohlmann, MS, CGC
Genetic Counselor/Clinic Coordinator, Cancer Genetics Clinic
Division of Molecular Medicine and Genetics, Department of Internal Medicine

Jane M. Nicholson, MD
Clinical Assistant Professor of Obstetrics & Gynecology and Internal Medicine

Stephanie B. Wechsler, MD
Clinical Assistant Professor of Pediatrics & Communicable Diseases, Division of Pediatric Cardiology; Clinical Assistant Professor of Internal Medicine, Division of Molecular Medicine and Genetics

Susan Chrysogelos, PhD
Division Administrator, Division of Molecular Medicine and Genetics, Department of Internal Medicine

** Our signatures represent our individual opinions and not necessarily the views of the University of Michigan

Contact information:
Wendy R. Uhlmann, MS, CGC
University of Michigan
Division of Molecular Medicine & Genetics
4301 MSRB III, Box 0638
Ann Arbor, MI 48109-0638
Phone: (734) 763-2532
Fax: (734) 763-7672
e-mail: wuhlmann@umich.edu

Goodwin, Suzanne (NIH/OD)

From: Walker M.D., Patricia [pwalker@svcmcny.org]
Sent: Monday, May 02, 2005 2:07 PM
To: Goodwin, Suzanne (NIH/OD)
Subject: Genetic counseling services

Dear Ms. Goodwin:

We have reviewed the SACGHS report regarding genetic counseling services and would like to commend you and the committee on an excellent and comprehensive document.

The Cystic Fibrosis Center at St. Vincent's Hospital hired one of the first genetic counselors to graduate from Sarah Lawrence College in 1971, and we have always employed the services of a genetic counselor - it is one of the aspects of our Center that distinguishes us from the other 114 CF Centers in the United States. In today's health care environment, it has become more difficult to justify this vital component of our multi-disciplinary program when the counselor is unable to bill independently for her professional services. The services provided by our counselor, Elinor Langfelder-Schwind, are extremely comprehensive and beyond the scope of training and expertise of any other professional on our team. It is most troubling to think that other disciplines might be assuming this unique role due to issues related to reimbursement.

I strongly suggest that the SACGHS report include a specific recommendation to add genetic counselors to the list of health care professionals who are eligible to bill Medicaid and Medicare as independent providers. Their well-qualified services and contributions more than warrant this distinction.

Thank you for your consideration,
Patricia Walker, M.D.

THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON
MEDICAL SCHOOL

DEPARTMENT OF PEDIATRICS
DIVISION OF MEDICAL GENETICS

6431 Fannin Street
Houston, Texas 77030

713 500 5760
713 500 5689 fax

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892
Email: goodwins@od.nih.gov
Fax: 301-496-9839

April 28, 2005

Dear Ms. Goodwin:

I am writing in regards to the SACGHS Draft Report on Coverage and Reimbursement of Genetic Tests and Services. I am a practicing genetic counselor and faculty member of a large urban university medical center. On a daily basis, I find myself in consideration of issues relating to the comprehensive provision of medical genetic services, and often struggle with the barriers placed upon my practice by the limitations genetic counselors face in being reimbursed for the services that we provide.

I applaud the SACGHS's efforts to elucidate the importance of medical genetic services and the unique reimbursement issues that practitioners such as myself face. I would like, however, to strongly encourage your committee to consider the following revisions to your draft in preparation of your final report:

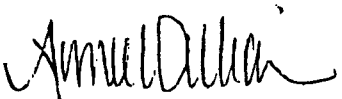
1 – Genetic counselors are **not** statutorily eligible to bill Medicare for the services we provide. While this point can be inferred from the text of your draft as it stands, I believe that it is in the committee's best interest to make this point specifically. Many practitioners of genetics (i.e. MD geneticists, nurse geneticists) are recognized providers per Medicare; making the point that such a large segment of providers, namely genetic counselors, are not, will help to seal the gravity of the reimbursement issues you discuss.

2 – The statement regarding establishing a mechanism to later determine which providers have the credentials necessary to be considered as reimbursable providers of genetic counseling services is, as it should be, inclusive of all

providers of genetic counseling services. I appreciate the advisory committee's desire not to leave any potential providers out of its recommendations. However, I will point out that genetic counselors, in particular, already have the appropriate credentials and training necessary to provide genetic counseling services. Given that we do comprise such a large percentage of genetic health care providers, I feel that our profession and its credentialing process should be particularly recognized. I see no reason not to point out genetic counselors as reimbursable providers, with the caveat that other eligible providers should be further identified and included in future efforts.

Thank you for the opportunity to comment on the advisory group's efforts; their work has resulted in a very comprehensive and educational report which I enjoyed reading. I, for one, appreciate the work the group has done on behalf of all genetic service providers. I hope that the advisory group will recognize, however, that the final report has the potential for impacting decisions made both by the government and by private payors. By more clearly specifying the hurdles to reimbursement faced by genetic counselors, a group that provides a large percentage of the medical genetic counseling services discussed in your draft, this document will better arm all genetic health care providers in making their pleas for better reimbursement in both the public and private health care sectors.

Sincerely,



Aimee Tucker Williams, MS, CGC
Assistant Professor

Goodwin, Suzanne (NIH/OD)

From: Williams, Janet Karen D [janet-williams@uiowa.edu]
Sent: Monday, March 28, 2005 3:04 PM
To: Goodwin, Suzanne (NIH/OD); Masny, Agnes
Cc: Communications and Advancement
Subject: FW: SACGHS Request for Public Comment

Good afternoon,

I am responding to the invitation to submit comments on the draft report on coverage and reimbursement of genetic tests and services. This document provides a summary of several key issues to be considered for this topic.

I would ask the committee to review the content of the document at the top of page 76 where it states (this is my rough replication) " therefore the ability to provide genetic counseling requires a knowledge base and skill set that is distinct from other professions". A preferred statement may be "therefore the ability to provide genetic counseling requires a knowledge base and skill set that is sufficient"

As I read the original statement, it appears that the sentence may be intending to communicate that specific knowledge and skills are needed. However, neither the sentence, nor the text prior to this sentence, provides evidence to link the full range of potential patient outcomes to professional identity of the healthcare provider. It strikes me that an assessment of outcomes of education and counseling regarding genetic health concerns moves away from the focus of this work, and may be beyond the scope of this document.

It is my impression that the body of knowledge linking patient outcomes with genetic health care, and other individual, family, and societal variables is small and has not consistently documented which factors are predictive of desired or undesired outcomes. Assessment of wellbeing of the public, with regard to use of genomic knowledge, is an complex task. While the identity of the health care provider may be one important factor, it is likely that other variables related to the individual, his/her family, societal, and health systems issues will also influence the outcome of receiving genetic information and counseling. This line of inquiry may be one for which our current research measures and methods may not be entirely sufficient.

Thus, I am urging the committee to reconsider this component of the report, to carefully avoid confusing conclusions regarding issues to be considered in billing and reimbursement, with factors influencing patient outcomes in persons who receive genetic health care services.

Thank you for the opportunity to comment on this important document. Please do not hestitate to contact me if I can be of assistance.

Janet Williams

JOHNS HOPKINS
UNIVERSITY

Department of Gynecology and Obstetrics
Division of Maternal-Fetal Medicine
The Johns Hopkins Hospital
600 N. Wolfe Street / Phipps 228
Baltimore MD 21287-1228
410-955-8496 / Fax 410-614-8305
Nights and Weekends
410-955-4331 or 410-955-5850

May 2, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

Re: Coverage and Reimbursement of Genetics Tests and Services

Dear Ms. Goodwin:

I am writing in support of the draft report of the Secretary's Advisory Committee on Genetics, Health, and Society with focus on the importance of billing for genetic counselors' services. As you know, genetic counselors are professionals who have completed a master's program in medical genetics and counseling. The certification of genetic counselors through the American Board of Genetic Counseling provides the means of identifying qualified health providers who should be eligible to bill directly for their relevant services. Genetic counseling is a critically important component of the appropriate use and integration of genetic tests and services. I further support the draft report's focus on a CPT evaluation and management system so that qualified genetic counselors are eligible for a National Provider Identifier and may utilize the full range of CPT evaluation and management codes available for genetic counseling services. I am in support of the Department of Health and Human Services (with input from providers of genetic counseling services) to conduct an evaluation of codes and their associated relative values and addressing any code inadequacies with respect to genetic counseling services.

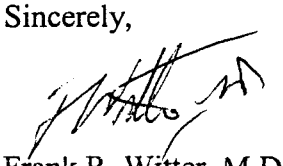
As Director of the Prenatal Diagnosis and Treatment Center at The Johns Hopkins Hospital, I can personally attest to the importance of the genetic counseling services at our own Institution. Our counselors work as members of our health care team, providing information and support to families who have members with birth defects or genetic disorders and to families who may be at risk for a variety of inherited conditions. They identify families at risk, investigate the problem present in the family, interpret information about the disorder, analyze inheritance patterns and risks of recurrence, and review available options with the family. They also provide supportive counseling to families, serve as patient advocates and refer individuals and families to community or state support services. They serve as educators and resource people for other health care professionals and for the general public. Our counselors also work in

administrative capacities and engage in research activities related to the field of medical genetics and genetic counseling. Genetic counselors require a knowledge base and skills that are distinct from other health care professionals. The family's ability to make informed decisions about genetic testing, medical management, and lifestyle depends on the qualifications and competence of the health professional providing genetic counseling services. Informed consent and test interpretation are critical to informed patient decision-making.

I also believe that reimbursement for genetic counseling services will provide decreased costs and increased access for patients and their families, as well as the entire health care system. Prenatal genetic counseling services provide for a higher magnitude of risk identification, more awareness at delivery, and subsequently, lower costs. I am particularly drawn to one potential harm of non-reimbursement of genetic counseling services. That being, that most centers which provide genetic counseling services no longer are funded by grant support. It is thus my fear that non-reimbursement for genetic counseling services could lead to possible career changes due to the lack of salary support; with the growing need for genetic counseling services, a decrease in qualified genetic counselors would make it more difficult to meet the needs, and there would be increasingly unequal access to such services.

In summary, I support that certified genetic counselors are highly qualified health providers, that their value and effectiveness have been well proven and established, and that they are cost-effective in the health care system. I further support a CPT evaluation and management system so that qualified genetic counselors are eligible for a National Provider Identifier and may utilize the full range of CPT evaluation and management codes available for genetic counseling services, and most of all, I support that they are eligible and should be able to bill directly for their relevant services. I wish to extend my sincere gratitude to the Secretary's Advisory Committee on Genetics, Health, and Society for their extensive efforts and focus on these crucial issues. Please do not hesitate to call upon me if I may be of any assistance.

Sincerely,



Frank R. Witter, M.D.
Associate Professor, Gynecology and Obstetrics
Director, Labor and Delivery

FRW/tcs

Goodwin, Suzanne (NIH/OD)

From: Milan & Janja Katic [katic@icongrp.com]

Sent: Saturday, April 02, 2005 5:57 PM

To: Goodwin, Suzanne (NIH/OD)

Subject: SACGHS Coverage and Reimbursement for Genetic Tests - Public Comment

I am a medical geneticist serving a 9-county area in northwest Indiana. Problems encountered in my practice with respect to reimbursement issues primarily relate to Medicaid and Medicare coverage. Medicaid patients account for approx. 1/3 of my patient population. I have found that Medicaid reimbursement in Indiana is grossly insufficient to allow genetic testing on our Medicaid patients when the test is performed out of state. As you are probably aware, no single state is capable of providing all of the genetic tests which are currently available. No out of state lab will accept responsibility for another state's poor. When appealing to Medicaid for adequate reimbursement in order to perform confirmatory diagnostic testing, I have consistently been denied. As a result, my Medicaid patients cannot get the testing performed which is recommended since they are unable to cover the remainder of the cost of testing out of pocket. Reimbursement is usually 50% or less of what is charged. This is a significant problem for those tests which cost approx. $2000, such as testing for Osteogenesis imperfecta, Stickler syndrome or breast/ovarian cancer susceptibility.

As a physician, I recognize that fees for genetic counseling provided by me would be higher than those charged by a genetic counselor. However, there are times when a physician is cost-effective. The ability of a physician to perform a physical exam and diagnose can reduce the number of tests suggested for diagnostic purposes. Furthermore, in this area of Indiana, there are no genetic counselors. I am the only genetics services provider. Regionalization of genetics services can save patients from having to travel long distances for care and can lead to timely diagnoses when genetics services providers can see patients within a few hours - e.g., newborns suspected of having a genetic condition - as opposed to having to wait until the patient can travel 2 or more hours to a medical center for their genetics evaluation.

Finally, I can understand the frustration of the insurance provider and the consumer with respect to genetic testing. Even if the test is covered, there are very few tests which can identify all affecteds, either because of heterogeneity of etiology or inability to identify all family-specific mutations by present testing methods. As a result, an answer cannot always be provided to a specific family, yet the cost of testing needs to be paid and is often considered high. Maybe we should compare our costs to the costs of routine MRI or CT scans which actually exceed the cost of even BRCA1 and BRCA2 testing - at least in northwest Indiana.

Janice Zunich, M.D.

Organizations

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

May 5, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892

RE: Comments on *Coverage and Reimbursement of Genetic Technologies and Services*, Draft Report of the SACGHS (April 2005)

Dear Ms. Goodwin:

On behalf of the Advanced Medical Technology Association (AdvaMed), I am pleased to provide the enclosed comments on the SACGHS April 2005 Draft Report on *Coverage and Reimbursement of Genetic Technologies and Services*. Most of these comments are technical in nature, and are intended to ensure that the reader fully understands the important coverage and reimbursement challenges facing genetic tests.

AdvaMed is the largest medical technology association in the world, representing more than 1200 medical device, diagnostic and health information systems manufacturers of all sizes. AdvaMed member firms provide 90 percent of the $75 billion of health care technology products purchased annually in the U.S., and nearly 50 percent of the $175 billion purchased annually around the world. AdvaMed member companies range from the largest to the smallest medical technology companies. Nearly 70 percent of our members have fewer than $30 million dollars in sales annually.

A large segment of our membership is devoted to the development of diagnostics, including molecular technologies, and we are very appreciative of your work to identify the coverage and reimbursement challenges facing genetic tests. In reviewing this draft report, we noticed that you have made substantial changes to the draft report (dated June, 2004) that was circulated last year, and that many of these changes reflect our previous comments. We want to thank you for your responsiveness, and we hope that these final comments assist as you move the report toward publication.

Thank you for your consideration. Please contact me with any questions or if you would like additional information.

Sincerely,

Carol A. Kelly

Enclosure

AdvaMed Comments
Coverage and Reimbursement of Genetic Tests and Services
Draft Report of the SACGHS
April 2005 Public Comment Draft

Preface, p. 7:

- First line of last paragraph, line 1: Typo—we think the word "comprising" should read "comprised."

Introduction, p. 10, second paragraph & box on page:

- Discussion of the report's goal--ensuring appropriate coverage and reimbursement for genetic tests. Suggestion: fine tune/edit the last two sentences to say:

  Rather, the Committee believes that genetic tests and services should be covered when there is adequate evidence to support their use. In addition, The Committee believes that reimbursement levels for covered tests should be set at levels that do not undermine this coverage or reduce appropriate patient access.

Genetic Tests & Services: Challenges to the U.S. Health Care System, pp. 13-18:

- Second paragraph, p. 13: needs editing. Suggestion: fine tune to say:

  Genetic tests and services face many of the same challenges other new medical technologies confront in being integrated into the health care system. They have to build a sufficient evidence base for both FDA pre-market regulatory clearances and approvals, and insurance coverage. In addition, genetic tests and services face a number of additional challenges due to a number of characteristics that are specific to these tests.

- Five characteristics of genetic tests discussed on pages 13-15: Not all of these characteristics have health financing implications or are unique to genetic tests. For example:

  The first characteristic, noted on page 13—the fact that genetic services involve a number of providers, presenting coordination of care challenges—seems characteristic of chronic diseases generally, and is not unique to genetic tests.

  The third characteristic, noted on page 14, second paragraph—genetic tests provide risk information for some diseases for which no treatments or clinical interventions exist—is not unique to genetic tests. This is also true for the fourth characteristic—the tests raise complex legal, ethical, societal, psychological, familial, and personal issues. Some non-genetic tests have this characteristic as well.

- The second characteristic, noted on page 13, bottom paragraph, is not clear to the reader.

  Is it the fact that disease onset is the accumulation of multiple risk factors (sentence one), or that no clinical interventions are currently available (sentence two), or that the overall risk of disease onset can be reduced because of preventive measures taken as a result of the genetic test (last sentence of top paragraph on page 14)? Further, it is not clear to the reader how any of these points presents a challenge for health financing.

Coverage, pp. 19-34:

- Section on *Coverage Decisions*, p. 19: In the paragraph identified as *Overview of Coverage Decision Making*, three tiers of coverage decision making are referenced. We find the discussion of "tiers" confusing. The first tier identified describes how Medicare officials approach the task of making coverage determinations—first identifying the statutory benefit category that applies. This first step is not relevant for private payers, while it is an important step for Medicare—given the role of Congress in determining the content of this health insurance program for the elderly, disabled, and ESRD patients. Because this section of the report applies to all health insurers in the United States, it might be best to take up this matter later, in the discussion of Medicare Coverage that begins on page 28. Also, the discussion of the third tier is a bit confusing. We think you only need to say that if an insurer has a coverage policy in place for a particular service or technology, the plan that processes the claim also is responsible for applying the policy to individual patient circumstances.
- In the paragraph identified as *Evidence-based Coverage Decisions* on page 21, you explain today's health care market with a parenthetical—the need for cost containment. We understand that you want to convey that there is pressure among insurers for cost-containment, but we do not think that you should imply to the reader that the current marketplace is characterized by cost-containment. The market could also include factors like patient desires for more access to genetic tests, more up-to-date procedures, less rationing, etc. If the point is that insurers tend to focus on cost containment, that point should be made. In the past few years, there has also been a reaction in the market against the more severe cost-containment approaches used by the managed care industry, as well as more assertiveness among patients to advocate for greater information on medical procedures and services and greater access to them. Also, the reference to the legal environment and medical liability leads one to think of increased patient access to more covered services—not cost containment.
- In the second paragraph of the discussion identified as *Evidence-based Coverage of Genetic Tests* on page 22, we think the second sentence could be made more clear and direct if edited as follows: *This is due to an historically lesser focus on translational research compared to basic research, which has hindered the collection and analysis of clinical data to satisfy evidence standards for coverage decisions.* In addition, we think that the next sentence (*If coverage decisions...costs may be high.*) is not clear and should be deleted.
- The box on page 22, titled "Considerations in Making Coverage Decisions for New Technologies," lists a series of factors which may—or may not—be considered by various insurers. The listing appears to us to be illustrative, and not based on any particular research, but it might lead the reader to conclude that they are always factored in by all insurers. Further, a number of the various possible considerations raise issues that might confuse the reader concerning how they might be applied in practice. Given this, we suggest deleting the box. It diminishes the points made in the text.
- Regarding the discussion of *Medicare Coverage* on page 28, we commented on this same language that appeared in the previous draft. We reiterate our concern: *it is not clear to the public when CMS will refer matters to MCAC and when it will not.* In fact, CMS is currently soliciting comments on a draft guidance document on this matter. Your language seems to imply when the conditions mentioned are met, "CMS will seek" MCAC's advice. In fact, these conditions are quite broad—and the draft guidance document contains even more circumstances where CMS *may—not will*—refer a matter to MCAC for advice. The explanation of MCAC might be better if it were re-drafted as follows: *In making national*

coverage determinations, CMS may request the advice of an expert advisory committee, the Medicare Coverage Advisory Committee (or MCAC), to assist in evaluating the evidence bearing on a matter. MCAC consists of a maximum of 100 appointed members—from which a panel of no more than 15 is drawn for any one meeting. CMS may refer topics to MCAC that are the subject of significant scientific, medical, or public controversy; where technology dissemination has the potential to have a major impact on the Medicare population, the clinical care of beneficiary groups, or the Medicare program overall; or where the NCD process would be better informed by more public input. All MCAC meetings are held in public.

- Regarding the discussion of *Local Coverage Determinations* on page 28, we have a similar comment to what we conveyed on your previous draft report. The Medicare Program Integrity Manual, at Section 13.7.1 states as follows: "...LCDs shall be based on the strongest evidence available." Therefore, we recommend the following language as a substitute to the second to last sentence in this discussion: *LCDs are based on empirical evidence, and they are typically developed with the input of expert medical opinion.*
- Regarding the discussion of *FDA Approval Requirement* on page 30, we reiterate the point we made on your previous draft. Medicare provides coverage and payment for items and services used in qualifying clinical trials—products not yet approved by the FDA.
- Regarding the discussion of *Application of Screening Exclusion to Genetic Tests* on pages 31 and 32, we suggest an edit in the first sentence (on page 31): *Since predictive and predispositional genetic tests are considered by Medicare officials to be screening tests...injury, CMS does not cover them.* This edit shows that it is CMS' judgment—not the words of the Medicare statute itself, that are the reason for non-coverage. Later in the paragraph, on page 32, mention is made of microarrays to test several different genes at one time for SNPs. We would like to reiterate our recommendation, made in response to the previous draft: *Apart from whether or not Medicare chooses to cover a particular pharmacogenomic test (these tests are not screening tests), there remains the issue of how Medicare will determine a payment rate given the fact that such tests provide results on several genes for a large variety of SNPs.*
- Regarding the discussion of *Increasing Receptiveness to Coverage of Preventive Services* on page 32, we suggest a full listing of the various prevention benefits added by Congress to the Medicare program.

Billing & Reimbursement, pp. 35-52:

- Regarding the discussion of *Coding Systems*, the last sentence on page 35 states that insurance payment is based on the dollar amount assigned to the code or codes. This is true for certain payment systems, but not others. For example, when tests are performed in an inpatient setting, the Medicare payment to the hospital is not based on the test code(s). It might be better to qualify your statement in light of this.
- Regarding the discussion of *CPT Codes for Genetic Tests* on page 36, it is worth noting that the use of method codes (absent a unique code for a particular new test) is not unique to genetic tests, and that this situation is not permanent, as the current wording implies. Rather, a unique code could be assigned by the CPT Editorial Panel.
- Regarding the discussion of *Category III CPT Codes* on page 37, you make the statement that these codes are not useful for some genetic tests—but you do not say why this is so.

- Regarding the discussion of the *Healthcare Common Procedure Coding System* on page 42, references should be made to "HCPCS," not to "HCPC."
- Regarding the discussion of *International Classification of Diseases Codes* on pages 42and 43, we think you should make clear that: there are both ICD-9 procedure and diagnosis codes; that CMS has the lead on assigning ICD-9 procedure codes and that the National Center for Health Statistics in CDC has the lead on assigning ICD-9 diagnosis codes; and that ICD-9 diagnosis codes are used by Medicare to document medical necessity. Therefore, claims submitted to Medicare for a genetic test must include not only the correct CPT or HCPCS code(s) but also an appropriate ICD-9 diagnosis code. Both national and local Medicare coverage determinations specify these codes.
- Regarding the discussion of the *Medicare Clinical Laboratory Fee Schedule* on page 43, we have several comments:
    - The discussion in the second paragraph gives the reader the impression that local carriers have flexibility in setting their rates, given the existence of the national fee schedule. This is not the case. In fact, the National Limitation Amount (NLA) is based on locally-set rates—and Medicare pays the lower of the billed amount, the local rate, or the NLA. It is not true that carriers may set the local payment at the national limit or at a lower rate.
    - In addition, the discussion of "gap fill" implies that there is a method that governs how carriers determine a "gap fill' amount for a new test code. The key point is that CMS has not provided adequate direction to its contractors, and that, as a result, these contractors vary widely in the approaches they take to assign "gap fill" rates—which are used by CMS to construct an NLA for new tests.
    - Further, your discussion of the CMS' *inherent reasonableness* authority on pages 44-45—and your potential recommendation that this mechanism be used to address variations in payment rates for genetic tests—should be carefully reconsidered. Medicare's record in using this authority has been such that industry has strenuously objected to both the procedures CMS has used and the inadequacy of data gathered for adjusting fee schedule rates. If SACGHS believes that the rates for genetic tests are not adequate, that they should reflect both their costs and values, we suggest that you recommend a means for CMS to arrive at such a rate. If this means consultations with genetic specialists, providers, laboratory specialists, and so forth, we suggest you make this point clearly, and not rely on the flexibility that inherent reasonableness provides the agency in setting prices that might not be appropriate.
- Regarding the discussion of *Clinical Diagnostic Laboratory Test Regulations* on page 45, second to last line: "HCPC" should be replaced by "HCPCS."

*****

May 5, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin:

This letter presents comments of the American Academy of Actuaries'[1] Committee on Federal Health Issues regarding "Coverage and Reimbursement of Genetic Tests and Services," an April 2005 report of the Secretary's Advisory Committee on Genetics, Health, and Society. We raise issues pertaining to four areas—genetic testing in general, health insurance markets, cost-effectiveness data, and the Medicare and Medicaid programs. We commend your initiative to address the complex and important issues surrounding genetic testing.

Genetic testing has been an area of great interest to the Academy and we have published a series of documents to provide education on the actuarial aspects of the issues related to genetic testing.[2] A clear understanding of genetic testing issues and the use of genetic information is needed so that rules governing their use can find the best balance between the need to better manage an already complex health care system, and the need to use genetic testing and the resulting genetic information for proven beneficial health care treatment. A full understanding of the issues would be useful in making coverage and reimbursement determinations as well.

Genetic Discrimination

In the preface of the report, the issue of potential genetic discrimination is raised in a sidebar. While genetic discrimination is not the focus of this particular report, the appropriate use of genetic information remains perhaps the single most debated public policy question related to genetic testing. The question is complex, and the issues involved differ among the various health insurance markets. We would draw your attention to the Academy issue briefs and monographs on risk classification and the use of genetic information which, when taken together, provide a thorough overview of the actuarial issues involved.

[1] The Academy is the public policy organization for actuaries of all specialties within the United States. In addition to setting qualification and practice standards, a major purpose of the Academy is to act as the public information organization for the profession. The Academy is nonpartisan and assists the public policy process through the presentation of objective analysis. The Academy regularly prepares comments on proposed federal regulations, and works closely with state officials on issues related to insurance. The Academy also develops and upholds actuarial standards of conduct, qualification and practice, and the Code of Professional Conduct for all actuaries practicing in the United States.

[2] See attachment "Academy Public Statements Related to Genetic Information" for a list of our public statements along with web links.

1100 Seventeenth Street NW Seventh Floor Washington, DC 20036 Telephone 202 223 8196 Facsimile 202 872 1948 www.actuary.org

Health Insurance Markets
The use of genetic testing and information will pose unique challenges in each health insurance market – group, non-group, public, private, etc. This is also an area that the Academy has examined in previous publications and it should be considered in discussions related to coverage and reimbursement of genetic tests. The report seems to focus more on the effect of genetic testing on Medicare and Medicaid, rather than its effect on the private employer and other insurance markets. The introduction of such technology could cause pricing problems and require different changes within each market. As you note in the report, historically if Medicare makes coverage changes, private employers may feel obligated to make similar coverage changes as well. Therefore, coverage and reimbursement changes in the private employer market, as well as the public health insurance market, could have broad implications and should be considered carefully.

Cost-Effectiveness Data
Another topic addressed in the report pertains to cost-effectiveness data. Cost-benefit data is very important and any clinical cost-effectiveness or cost-benefit data should be expanded to the program level basis. Additionally, any such data used to make coverage decisions in the Medicare or Medicaid programs should involve the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS).

Medicare and Medicaid
The report includes some potential recommendations related to coverage and reimbursement of genetic tests and services under Medicare and Medicaid. Any such recommendations should be considered within the context of the long-term financing of these programs.

In particular, Medicare faces serious long-range financial problems. Medicare's financial condition is a key health care issue for the Academy and we have developed many publications over the past several years related to the long-term financing of this program.[3] The *Medicare Prescription Drug, Improvement, and Modernization Act*, which is one of the largest benefit expansions made to the Medicare program, has not yet been fully implemented. The likely cost of the new prescription drug benefit has been the subject of much debate, and the full impact that the new program will have on Medicare's finances will not be realized for several years. Any further expansion of Medicare benefits should be approached cautiously and should be considered in the context of the long-term financing of the Medicare program. In particular, adding coverage for genetic tests or treatment to the Medicare program without fully offsetting the associated cost would exacerbate the program's long-term financial difficulties.

With states cutting back on Medicaid benefits, the addition of benefits under the Medicaid program could also be problematic. While Medicaid doesn't have the same long-term trust fund financing as does Medicare, it is ultimately funded through general revenues at the federal and state levels and recently has been experiencing budget constraints that could make it difficult to offer coverage for genetic testing and services.

[3] The Academy's many Medicare publications are available on the web at http://www.actuary.org/medicare/index.htm.

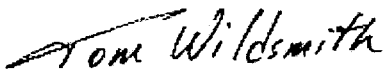
Therefore, before any coverage changes are made to Medicare or Medicaid, we recommend that in addition to clinical cost-effectiveness studies, the impact on the long-term financing of these public programs be considered. Specifically, we suggest that the cost-benefit evaluation process be extended to include a CMS Office of the Actuary projection of the long-term impact on Medicare and Medicaid benefit payments and revenues.

The Academy seeks to provide objective actuarial analysis of issues pertaining to genetic testing. We appreciate your efforts to address these complex and important issues and hope you find our comments helpful as this debate continues.

Members of the Academy are available to work with you on issues related to genetic testing. If you would like to discuss these issues further, please contact Academy senior health policy analyst (federal) Holly Kwiatkowski at 202-223-8196 or *Kwiatkowski@actuary.org*.

Sincerely,

Alfred A. Bingham, MAAA, FSA
Chairperson, Committee on Federal Health Issues
American Academy of Actuaries



Thomas F. Wildsmith, MAAA, FSA
Vice Chairperson, Committee on Federal Health Issues
American Academy of Actuaries

Academy Public Statements Related to Genetic Information

The Academy's Health Practice Council has developed a series of documents to provide education on the actuarial aspects of the complex issues related to genetic information. The following documents are available on the Academy's website:

- Statement to the House Education and the Workforce Subcommittee on Employer Employee Relations regarding the use of genetic information in health insurance (July 22, 2004)
  http://www.actuary.org/pdf/health/genetic_22july04.pdf

- Letter to Congress regarding the use of genetic information in health insurance (May 22, 2003)
  http://www.actuary.org/pdf/health/genetic_22may03.pdf

- Issue brief *The Use of Genetic Information in Disability Income and Long-Term Care Insurance* (Spring 2002)
  http://www.actuary.org/pdf/health/genetic_25apr02.pdf

- Issue brief *Risk Classification in Voluntary Individual Disability Income and Long-Term Care Insurance* (Winter 2001)
  http://www.actuary.org/pdf/health/issue_genetic_021601.pdf

- Monograph *Genetic Information and Medical Expense Insurance* (June 2000)
  http://www.actuary.org/pdf/health/geneticmono.pdf

- Issue paper *Risk Classification in Individually Purchased Voluntary Medical Expense Insurance* (February 1999)
  http://www.actuary.org/pdf/health/risk.pdf

- Issue brief *Genetic Information and Voluntary Life Insurance* (Spring 1998)
  http://www.actuary.org/pdf/life/genet.pdf

- Issue brief *Risk Classification in Voluntary Life Insurance* (Spring 1997)
  http://www.actuary.org/pdf/life/riskclas.pdf

Advancing
Clinical Laboratory
Science Worldwide

May 6, 2005

Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Secretary's Advisory Committee on Genetics, Health and Society's (SACGHS's) draft report on "Coverage and Reimbursement of Genetic Tests and Services." We agree changes need to be made to the current payment process to ensure that laboratories are adequately paid for genetic testing. Our specific comments follow:

Genetic Nondiscrimination

AACC agrees that federal legislation is needed to bar health insurers and employers from discriminating against individuals solely on the basis of genetic information. Without legislative protections, patients might refuse medically necessary genetic testing because they fear that insurers or employers would use it to deny them insurance coverage or employment. AACC believes it is essential, therefore, that genetic data remain confidential between a patient and his or her physician.

Definition of Genetic Tests

AACC suggests that you shorten the section "What are genetic/genomic tests and technologies?" (on page 16), which is lengthy and confusing. In addition, we recommend that you include a smaller box within the text that states that genetic testing, for the purposes of this document, relates to heritable mutations (since this seems to be the intent of the committee).

Principles for Making Genetic Testing Coverage Decisions

AACC agrees that CMS should develop criteria, in conjunction with the appropriate stakeholders, which can be used to determine whether a genetic test should be covered. Similarly, the Association recommends that CMS develop an evidence-based guidance document for Medicare and its local contractors, which outlines the types and quality of data needed to evaluate and determine coverage for new technologies. The development of such guidance would assist public and private payers make coverage decisions, while more clearly delineating for device manufacturers and clinical laboratories what data needs to be provided to obtain a coverage determination.

Translating Local into National Coverage Policies

Currently, Medicare and each of its local payers determines on its own what type and level of evidence is necessary to justify coverage of a test. Unfortunately, this patchwork process requires medical device manufacturers and clinical laboratories to duplicate efforts when seeking local coverage determinations from the 36 carriers and fiscal intermediaries. Since each of these contactors has its own process for making these determinations, the result is often inconsistent and conflicting coverage decisions among contractors.

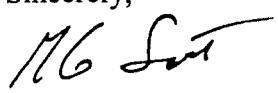
AACC suggests that CMS establish a mechanism whereby a test is automatically forwarded for a national coverage decision (NCD) once it has been approved by a certain number of contractors, possibly one-third. This would eliminate coverage disparities of around the country and reduce the burden on the health care entities pursuing coverage decisions, while also preserving the flexibility that local entry offers for new technologies.

New Process for Determining Covered Screening Tests

AACC agrees that a mechanism should be created that permits CMS to assess whether the evidence indicates a genetic test is "reasonable and necessary for the prevention or early detection of an illness or disability and, thus, ought to be covered." The current process, which is lengthy and inefficient, requires that Congress make such decisions on a test by test basis. We believe giving CMS this authority will lead to more timely decisions, greater patient access to valuable laboratory tests and improvements in patient care.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (314) 362-1503, or Vince Stine, Director, Government Affairs, at (202) 835-8721.

Sincerely,



Mitchell G. Scott, PhD
President, AACC

The American Board of Genetic Counseling

9650 Rockville Pike • Bethesda, MD 20814-3998 • (301) 634-7300 • FAX (301) 634-7320

May 5, 2005

Reed V. Tuckson, MD
SACGHS Chair
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Re: Draft recommendations on coverage and reimbursement

Dear Dr. Tuckson,

I am writing as the American Board of Genetic Counseling (ABGC) representative to SACGHS and as a member of the ABGC Board of Directors and would like to provide comment on the committee's recently published draft recommendations on coverage and reimbursement for genetic tests and services.

In particular, I would like to comment on the potential recommendations listed on page 52, specifically the statement: "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." At the end of the meeting on March 1, 2005, I left with the impression that after much discussion about this serious and complicated issue, the committee voted and was ready to support the recognition of board certified genetic counselors and certified advanced practice genetic nurses as qualified providers. No public comment was provided against this recommendation nor were there other groups requesting recognition.

In creation of the working group report we provided at the request of SACGHS, evidence was presented that certified genetic counselors and advance practice nurses in genetics are currently providing the bulk of genetic counseling services in the United States and are recognized by the medical community as the appropriately trained and credentialed individuals to do so. We feel SACGHS should produce a stronger statement which supports the qualifications of these providers and their ability to bill directly for their services.

I offer a draft rewrite of the statement below;
Qualified health providers which currently includes board certified genetic counselors (ABGC/ABMG) and advanced practice nurses with the APNG credential provided by the GNCC should be considered qualified providers and allowed to bill directly for genetic counseling services. The Secretary should expeditiously identify an appropriate mechanism for validating the credentials of approved providers and determining the credentials and criteria needed for other non-physician health providers to be deemed qualified to provide genetic counseling services and eligible to bill directly for them.

The committee also agreed that an oversight group was needed to consider other qualified professionals and better define the qualifications for recognition as providers of genetic counseling. I understand that there are other groups that will want to be considered – single gene counselors and/or sickle cell counselors – but currently there is no recognized body or process to credential these individuals. Developing an oversight body that includes these service providers will likely require a timely process and we believe certified genetic counselors and nurses should be recognized now. I would like to assure you that ABGC remains committed to this issue and is willing to contribute to the process.

I appreciate the opportunity the SACGHS has given me personally and the ABGC to participate in this discussion and process and look forward to continuing to work together to improve the delivery of genetic services to the American public.

Sincerely,

Andy Faucett, MS, CGC
ABGC Representative to SACGHS
ABGC Credentials Chair

Anne Greb, MS, CGC
ABGC President
For the ABGC Board of Directors

Cc: Suzanne Goodwin
Cynthia E. Berry, JD

American
Clinical Laboratory
Association

Comments of the American Clinical Laboratory Association
Secretary's Advisory Committee on Genetics, Health, and Society's Draft Report
"Coverage and Reimbursement of Genetic Tests and Services"
May 4, 2005

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the draft report of the Secretary's Advisory Committee on Genetics, Health, and Society entitled "Coverage and Reimbursement of Genetic Tests and Services." ACLA is an association representing independent clinical laboratories throughout the United States including local, regional and national laboratories. In the United States alone, clinical laboratories perform millions of tests each year for physicians and other health care professionals. ACLA members are regularly engaged in the development and performance of new types of testing, including genetic testing, to help assess, monitor, diagnose and treat diseases and medical conditions. As a result, ACLA members have a keen interest in the current state of coverage and reimbursement of genetic tests and services and how current mechanisms for coverage and reimbursement of genetic tests and services can be improved.

Laboratories today offer a wide range of testing services, from simple blood test to highly sophisticated genetic analyses. With the mapping of the human genome, it has become common for laboratories to offer genetic testing, which can identify specific genetic mutations that may indicate the presence (or absence) of disease or particular conditions. Many of these genetic tests, such as tests for cystic fibrosis, Factor V Leiden or Fragile X, were first developed in the laboratory and are now standard in the treatment of patients. Genetic testing has the potential to provide more precise information about an individual's susceptibility to disease and response to pharmaceuticals.

As stated in the introduction, the draft report has two main purposes: to describe the current state of, and problems associated with, coverage and reimbursement of genetic tests and services and to offer recommendations on how current mechanisms for coverage and reimbursement of genetic tests and services might be improved. ACLA generally concurs with the draft recommendations proposed by the committee and believes they will, if implemented, make inroads into improving access to and utilization of genetic testing and services by addressing coverage and reimbursement throughout the health care system. We are attaching a document that details our suggested changes that we believe would clarify specific sections of the draft report.

ACLA welcomes the opportunity to participate in the development of appropriate coverage and reimbursement policy for genetic testing and services. We look forward to working with the Committee as you consider the broad range of human health and societal issues raised by the development and use of genetic testing.

1250 H Street, NW, ·Suite 880 ·Washington, DC 20005 ·(202) 637-9466 · Fax: (202) 637-2050

Coverage and reimbursement of Genetic Tests and Services

Page #	Section	Recommendation
13	First paragraph: Since Individuals genetic information does not change over time, a specific genetic test *only has to be performed once in their lifetime.*	We are concerned about this comment and feel that clarit needed. ▪ What about new technologies that can identify diseas not previously identified on same test? ▪ What about Pharmacogenomics? ▪ What about CF, more mutations are identified all the time that could result in retesting patients already test ▪ Interpretations and information can change ▪ What about diseases or conditions that result in genet mutations due to smoking, environmental exposure, (that may result in diseases or medical conditions?
16	Second paragraph: ....whether detected using DNA, RNA, Chromosomal analysis, or proteins	▪ Chromosomal analysis needs to be added ▪ Clarify that proteins are intended not to include prote such as cholesterol, etc. ▪
16	Third paragraph:	▪ Delete the last sentence starting with "There are presently 783....." and footnote [1] ▪ This information changes on a daily basis, would not recommend that
21	Evidence-based Coverage Decision.	▪ ...for clinical use have ~~required~~ change to encouraged
21	Technology Evaluation Center (TEC)	Comments about the TEC process for labs ▪ Problem when trying to apply to laboratory testing ▪ Criteria to tight and does not necessarily apply to lab:
22	Considerations in Making Coverage Decisions for New technologies	1. Is it FDA approved, cleared or not subject to FDA premarket review 2. Delete **"How much does it Cost?** ▪ Replace with "Is it cost-effective" ▪ Focus on cost effective vs cost ▪ Focus on improvement of patient care 3. Delete How much money will this new technology sa us?

Comment:

Page #	Section	Recommendation
22	Evidence-based Coverage of Genetic Tests …that is relevant to the populations the health insurance ….	▪ The concern is that analytical validity is not relevant specific population
24	…Although covering a genetic test or service will generally increase overall health care …	▪ Although covering a genetic test or service ~~will~~ may ~~generally~~ increase ~~overall health care~~ spending on te or related services, from a…. Appropriate testing c result in overall lower cost of treating a patient or overall health care
26	Potential Recommendation	▪ Delete second sentence: "The principles should .. zone" ▪ Define therapeutic and informational service
26	Potential Recommendation	▪ Find Private Sector Solutions
26	Potential Recommendation	▪ Add Clinical Laboratories to ACCE/EGAPP Committees
27	Potential Recommendation "pediatrics and those with a prevention component.."	▪ Provide definition and clarity to scope – prevention component?" o What about other populations? Carrier status ▪ Tie back to recommendation on previous page
30	FDA Approval Requirements	▪
32	First Paragraph ***Potential Recommendations: We strongly support the recommendation***	▪ Concerned about the discussion with microarray, pharmcogenomic etc. – ACLA feels it may be outda quickly
34	Potential recommendation	▪ Use a Genetic Counseling consortium – experts in th state to determine how to disseminate the informatio
37	CPT Codes for Genetic Counseling	▪ Recommend that there be CPT codes implemented th would support the Pathology and Laboratory codes ▪ Ensure that Cytogenetics is included in the definition "genetics"

Page #	Section	Recommendation
45	Potential Recommendation	▪ New Language – In many cases, payment rates for genetic tests are lower then the actual cost of perform the test. CMS should explore alternatives to addre appropriate reimbursement.
52	Potential Recommendation	▪ 2nd bullet – "define reasonable and necessary" ▪ 3rd bullet - add "codes should represent all non-physician providers as well as laboratories" ▪ 5th bullet – "change ~~professionals~~ to providers
54	Potential Recommendation	▪ Need to add a sentence regarding the "intent of the dissemination of case studies is for educational purposes"

American College of
Medical Genetics
9650 Rockville Pike
Bethesda, MD 20814
Telephone 301-634-7127
Fax 301-634-7275
www.acmg.net

May 5, 2005

Secretary's Advisory Committee on Genetics, Health and Society (SACGHS)
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Dr. Tuckson and Members the Committee:

The American College of Medical Genetics (ACMG) is pleased to have this opportunity to comment on the *Draft Report: Coverage and Reimbursement of Genetic Tests and Services.* The American College of Medical Genetics represents more than 1350 biochemical, clinical, cytogenetic, medical and molecular geneticists, genetic counselors and other health care professionals committed to the practice of medical genetics in the United States, most of whom are Board certified by the only board of the American Board of Medical Specialties (ABMS) that is specific to this area of medical practice, the American Board of Medical Genetics (ABMG).

The ACMG engages in activities that advance the practice of medical genetics, ranging from promulgating laboratory and practice guidelines to advocating for fair health policies; increasing access to genetic services and improving the public's health; and promoting development and implementation of methods to diagnose, treat and prevent genetic disease. Issues related to the reimbursement of genetic tests and services are a central and critical concern to the sustenance of the specialty of medical genetics, and the ability of geneticists to provide high quality patient care, making the SACGHS's both relevant and timely to us. As such, we offer the following comments for your consideration.

The report captures many of the historical problems in billing and reimbursement for genetic services and provides an informative overview of the system. We commend the Committee for taking a proactive role in addressing these issues in order that the American public have access to high quality genetic services. I will comment on some areas that have been omitted and follow with specific comments on some of the areas included in the report.

- The CPT codes listed in your table of "Genetic Test Codes" are only a partial listing. Codes in the 882XX series that apply to cytogenetics and molecular cytogenetics are not acknowledged yet similar issues surround them. Many of these codes directly apply to prenatal

- Diagnostic tests and other genetic tests and should be similarly acknowledged. Further, there are a number of analytes and test methodologies in biochemical genetics that are omitted. Many of these are used in the diagnosis and follow-up of newborn screening for genetic diseases in the US and are among the highest volume genetic tests done in this country. The issues discussed in the report apply to them as well as to the molecular diagnostic subset of codes that is offered. The report should more broadly reflect the full range of testing for heritable disorders and traits since many of anticipated areas of high volume testing for genetic diseases will not be done by molecular tests but rather by functional tests that reflect an underlying genetic condition.

- The report correctly recognizes that there are groups of practitioners in addition to the genetic counselors who may provide genetic counseling services. Many of the doctoral level board certified laboratory directors as well as those individuals board certified as PhD Medical Geneticists provide genetic counseling, often for the very complex laboratory test results that may arise with their laboratories or clinical services. Language in the report should preclude their ability to continue to provide these services.

- You are correct in your presentation of the issues that impede the ability of genetic counselors to bill and be reimbursed for their services. It is also important to acknowledge a similar problem that faces the non-physician doctoral level laboratory directors who must interpret the results of their laboratory tests. These individuals comprise about 35-40% of the laboratory directors of heritable disease testing laboratories in the United States. Their training and board certification is recognized under the CLIA regulations as sufficient for their laboratories to be CLIA licensed. Many function as independent laboratories in either the private sector or within academic institutions. They are board certified by the ABMG and, with the MDs also board certified by ABMG, are recognized by the ABMS.

  In recent years, the ability of these laboratory directors to bill and be reimbursed for the professional components of the services provided by their laboratories has been severely compromised. This has occurred because the reimbursement for result interpretation has been made a professional component by virtue of having assigned the associated RVUs to the interpretive codes only when a -26 modifier code is attached to the base CPT codes (88291 and 83912). As such, they often have to find clinicians considerably less familiar with the technologies employed and the test results being interpreted in order to be reimbursed. In order to ensure that those who are best trained to interpret the results of the testing done in their

laboratories, we recommend that SACGHS consider that solutions similar to those suggested for genetic counseling be pursued. In particular, inclusion of these individuals under the listing of non-physician provider groups who receive statutory benefits under Medicare law seems an obvious solution. Alternatively, adequate reimbursement can be assigned to the base codes.

- While the report accurately acknowledges the deficiencies in the number of individuals trained and board certified in medical genetics, it doesn't adequately address some of the forms of practice that are evolving that can extend their services into local communities where their availability is most limited. In particular, telegenetics is a rapidly developing mode of service delivery, particular when education and laboratory test result communication are the goal. It should be appreciated that aspects of telemedicine billing and reimbursement will be inadequate for the telegenetics services. For instance, reimbursement has been focused around services provided to rural frontier communities. Although this may be appropriate for other subspecialists who are available in greater numbers, it is inadequate for genetics. As we seek mechanisms of delivering such services to the considerable numbers of individuals in small and medium sized cities that are also limited in their access to trained genetics service providers, it will be important to anticipate barriers such as these.

Turning to more specific comments:

- You appropriately acknowledge the large number of genetic tests currently available as clinical tests and research tests. The large number of tests that are also available while in the clinical investigational stage should also be acknowledged.

- Pg. 25 - footnote 24: Given that the vast majority of tests currently integrated into newborn screening in the United States are for rare genetic diseases, it seems inaccurate to suggest that such tests are inappropriate for broad screening purposes. Although incidence of conditions is a criteria by which tests are commonly assessed, there are others such availability of treatment that are equally important.

- Pg. 30: It should be recognized that FDA approved tests may also be delivered as home brew tests.

- Pg. 32 and 49: Information previously presented at SACGT meetings indicated that because genetic counselors were not recognized as a non-physician provider group under Medicare rules, there services could not be reimbursed as "incident to" services. The explanation provided in these sections seems to be a contrary view.

- Pg. 37: It should be recognized that the current CPT codes for all areas of genetics were done through the ACMG in 1997. The development of gene-specific codes was also done by the ACMG. Although not part of the Pathology Coding Caucus, the ACMG led many of the activities of that group and will continue to lead the development of coding in all areas of genetic services.

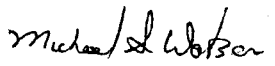
- Pg. 38: The organization you refer to under planned revisions is the ACMG, not the ACHG.

- Pg. 42: It should be recognized that there has been considerable evolution of ICD coding for genetic conditions, similar to those for CPT codes. A significant number were added in October 1994.

- Pg. 52: See prior comments on those from the genetics community who may provide genetic counseling services.

We appreciate the opportunity to comment on the SAGHS report on Coverage and Reimbursement of Genetic Tests and Services. We are available to the Committee for additional information if needed and look forward to working with you in the future.

Sincerely,



Michael S. Watson, PhD, FACMG
Executive Director

POWERS PYLES SUTTER & VERVILLE PC
ATTORNEYS AT LAW

Twelfth Floor
1875 Eye Street, NW
Washington, DC 20006-5409
Phone: (202) 466-6550
Fax: (202) 785-1756
www.ppsv.com

JAMES C. PYLES
(202) 872-6731
Jim.Pyles@ppsv.com

May 6, 2005

Via E-mail to Goodwin@od.nih.gov and Facsimile to (301) 496-9839

Secretary's Advisory Committee on Genetics,
Health, and Society
Attn: Susan Goodwin
NIH Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750
Bethesda, MD 20892

Re: Response to Request for Public Comment on Draft Report On Coverage and Reimbursement of Genetic Tests and Services

Dear Ms. Goodwin:

These comments are provided on behalf of the American Psychoanalytic Association (APsaA) and its more than 3000 members nationwide in response to the request for comments on the draft report on coverage and reimbursement of genetic testing and services published in the Federal Register on April 4, 2005 (70 Fed. Reg. at 17,085). We appreciate the opportunity to provide these comments and would be glad to meet with you and your staff to discuss them further.

APsaA has a long history of advocating for ethics-based medicine, particularly as it pertains to the traditional right of patients to not have their personal identifiable health information used and disclosed without their consent and against their will. This ethics standard is reflected in the Hippocratic Oath administered by 98% of medical schools in this country and in the ethics standards of the American Medical Association, APsaA and nearly every other segment of the medical profession.

We were pleased to see that the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) was charged with (a) studying the "clinical, ethical, legal and societal implications" of genetic testing; (b) analyzing uses of genetic information in insurance including health insurance; and (c) serving as a public forum for discussion of "emerging scientific, ethical, legal and societal issues raised by genetic tests". Draft at 3.

We are concerned, however, that the draft report fails to address these issues within the SACGHS' charge. For example, the draft report states that the Committee ranked coverage and reimbursement as "a high priority" because of the need to ensure appropriate access to genetic tests and "unmet data needs" that are limiting clinical integration. Report at 7. The report also notes that unlike other medical tests, genetic tests raise "complex legal, ethical, societal, psychological, familial, and personal issues", including concerns about privacy, and that "there are no guidelines for balancing the provider's duty to warn family members of their genetic risk for heritable disease against the mandates to preserve the privacy of the patient." Report at 14.

Further, the report contains the following "potential recommendation":

> 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 the HHS resources to develop and make widely available reliable and trustworthy information about family history, genetics, and genetic technologies to guide and promote informed decision making by healthcare consumers and providers. Such information should be made available information [sic] through federal government websites and other appropriate mechanisms.

Report at 55.

APsaA believes that the report should be modified to state clearly that **any use or disclosure of genetic information should be in accordance with established standards of medical ethics as well as federal and state law.** The draft report contains no discussion of standards of medical ethics and only briefly mentions in Appendix B that the State law of Massachusetts requires that an individual be informed of the availability of genetic counseling and that the laws of Michigan and New York require informed consent for genetic tests, "but do not specify who should provide such consent". Report at 78. The Report thereby ignores a large amount of federal and state law providing detailed standards for the use and disclosure of genetic information and misstates the limited law that is cited.

Any recommendations of insurance coverage or reimbursement of genetic testing information must address existing law and ethics standards pertaining to highly personal health information. HHS has determined that "[p]rivacy is a fundamental right". 65 Fed. Reg. at 82,464 (Dec. 28, 2000).* That right includes the right to privacy for highly personal health information as protected under the 4th and 5th Amendments to the U.S. Constitution. Id. There is increasing public concern about the loss of personal privacy and one of the three principal reasons for that concern is the risk of disclosure of genetic information through the use of electronic health information technology. 65 Fed. Reg. at 82,466.

The draft report contains findings that 45% of patient care fails to comply with evidence-based guidelines and that between 44,000 and 98,000 people die each year due to preventable medical errors. Report at 9. However, the report fails to cite HHS findings that 63% of the public would refuse to take a genetic test if their insurers or their employers could gain access to the results. NIH found that 32% of eligible people who were offered a test for breast cancer risk declined to take it, citing concerns about loss of privacy and the potential for discrimination in health insurance. 65 Fed. Reg. at 82,466. The report also does not mention HHS findings that each year nearly 600,000 people do not seek earlier treatment for cancer and more than 2 million people do not seek treatment for mental illness due to privacy concerns. 65 Fed. Reg. at 82,777-79. According to HHS, "[t]here are important societal benefits associated with improving health information privacy." 65 Fed. Reg. at 82,776.

Traditional standards of medical ethics state that, "The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law." AMA Ethics Standards E-5.05. As HHS has noted, "conflicts between a patient's right to privacy and a third party's need to know should be resolved in favor of the patient, except where that would result in serious health hazard or harm to the patient or others." See 65 Fed. Reg. at 82,472, citing AMA Policy No. 140.989.

Nearly all states recognize a common law physician-patient privilege under which personal health information may not be used and disclosed without the patient's consent. See, e.g., Givens v. Mullikin, 75 S.W. 3d 383, 407 (Tenn. 2002).

Even a cursory review of state law reveals that most states have enacted statutes conferring special and detailed privacy protections for highly sensitive health information such as information pertaining to cancer, HIV/AIDS, sexually transmitted

* These findings were made initially under the Clinton Administration but subsequently adopted by the Bush Administration when it put the HIPAA Original Health Information Privacy Rule into effect after conducting its own rulemaking proceeding. 66 Fed. Reg. at 12,434, 12,738.

diseases, drug and alcohol abuse treatment, mental health, and genetic testing. See generally state-by-state analysis prepared by the Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, www.legislature.state.al.us.

At least 35 states have enacted statutes specifically conferring special privacy protections for genetic testing information. Ala. Code § 27-53-2; Ariz. Rev. Stat. § 12-2802; Ark. Code Ann. § 23-66-320; Cal. Civ. Code § 56.17; Cal. Ins. Code §§ 742.407 and 10123.35; Colo. Rev. Stat. Ann. § 10-3-1104.7(3); Del. Code Ann. tit. 16 § 1220; Fla. Stat. Ann. §§ 627.4301 and 760.40; Ga. Code Ann. § 33.54-3; Haw. Rev. Stat. §§ 431:10A-101, 431:10A-118, 432D-26; 410 Ill. Comp. Stat. 513/15 and 513/30; Ind. Code Ann. §§ 27-8-26-2, 27-8-26-6, 27-8-26-7, and § 16-39-5-2; La Rev. Stat. Ann. §§ 22:213.7(C) and 22:213.7(E); Me. Rev. Stat. tit. 22 § 1711-C 2; Md. Code Ann. Ins. § 27.909; Mass. Gen. Laws ch. 111, §§ 70E and 70G; Mich. Comp. Laws § 333.17020; Minn. Stat. § 72A.139; Mo. Rev. Stat. § 375.1309; Mont. Code Ann. § 33-18-904; Neb. Rev. Stat. § 44-7, 100; Nev. Rev. Stat. § 629.181; N.H. Rev. Stat. §§ 141-H:2, 141-H:4; N.J. Stat. §§ 10:5-47, 17B:30-12; N.M. Stat. Ann. § 24-21-3; Ohio Rev. Code Ann. §§ 1751.64, 3729.46, 3901.49, 3901.50; N.Y. Civ. R. Law §§ 79-1(2)(b), 79-1(3)(a),79-1(6), and § 2612(b)(6), (d), (f), (g) and (h); Okla. Stat. tit. 36, § 3614.2, 3614.1; Or. Rev. Stat. §§ 192,535, 192.539; R.I. Gen. Laws §§ 27-18-52, 27-19-44, 27-20-39, 27-41-53, and 28-6.7-1; S.C. Code § 38-93-30, 38-93-40; S.D. Codified Laws, §§ 34-14-22, 58-1-25; 4 Utah Code Ann. § 26-45-104; 18 Vt. Stat. Ann. §§ 9332, 9334; Va. Code Ann. §§ 38.2-508.4, 40.1-28.7:1; Wis. Stat. Ann. § 631.89; Wyo. Stat. Ann. § 14-2-109.

These statutes generally provide, consistent with standards of medical ethics, that genetic testing information may not be used or disclosed without the express written informed consent of the subject of the test. Further, many provide that insurers may not require or request genetic information directly or indirectly or even whether an individual has taken or refused to take a genetic test as a condition of providing, renewing or limiting health insurance coverage. Most of these statutes also require the individual to be given detailed notice of his or her right to refuse genetic tests and to limit the further use and disclosure of this information. Further, these statutes often strictly limit the retention of genetic information without the patient's informed written consent. Finally, nearly all of these statutes provide a right of action for individuals to enforce these genetic privacy protections.

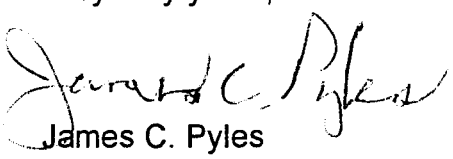
Contrary to the description in the draft report, the state statutes of Michigan and New York expressly require the written informed consent of the subject of the genetic test in order for the information to be disclosed. Mich. Comp. Laws § 333.17020; N.Y. Civ. R. Laws §§ 79-1(6), 79-1(2)(b).

APsaA does not believe that these state laws can be supplanted or circumvented by providing for genetic counseling or enacting federal laws prohibiting genetic discrimination as the draft report suggests. Report at 11 and 78. Medical ethics, the federal constitution, and state statutory and common law all give individuals a "fundamental right" (according to HHS) to medical privacy which includes the right to not have information regarding genetic tests used or disclosed without the individual's written informed consent.

While APsaA recognizes the value of "evidence-based" medicine (Report at 9), we believe that this interest cannot supplant the overriding importance of "ethics-based" medicine. The standards for ethics-based medicine with regard to genetic information are clearly set forth in the statutory and common law of most of the states. Those laws specifically address the use and disclosure of genetic information in the insurance setting. Accordingly, any report on insurance coverage and reimbursement of genetic testing, must incorporate these standards. Under no circumstances should an individual's genetic information or information about his or her family history be placed on the internet without the individual's written informed consent. Report at 55.

Please do not hesitate to contact us if you need further information.

Very truly yours,



James C. Pyles
Counsel
American Psychoanalytic Association

AMERICAN
SOCIETY FOR
MICROBIOLOGY

Public and Scientific Affairs Board

May 6, 2005

Secretary's Advisory Committee on
Genetics, Health, and Society
Department of Health and Human Services
Attn: Suzanne Goodwin
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

To Whom It May Concern:

The American Society for Microbiology (ASM) would like to take the opportunity to provide comments in response to the Request for Public Comment on the Draft Report on Coverage and Reimbursement of Genetic Tests and Services that was developed by the Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) and published in the *Federal Register* on April 4, 2005 (Volume 70, Number 63, Pages 17085-6).

The ASM is the largest educational, professional, and scientific society dedicated to the advancement of the microbiological sciences and their application for the common good. The Society represents more than 43,000 microbiologists, including scientists and science administrators working in a variety of areas, including biomedical, environmental, and clinical laboratory medicine. Many of ASM's members are individuals responsible for directing clinical microbiology, clinical immunology and molecular diagnostic laboratories, individuals licensed or accredited to perform such testing, industry representatives marketing products for use, and researchers involved in developing and evaluating the performance of new technologies. Thus, our Society has a significant interest in the process of establishing reasonable coverage and reimbursement for medically necessary genetic tests and services to ensure quality patient care for Medicare beneficiaries and for individuals insured by other third party payers.

The discipline of clinical microbiology also represents the initial area in which molecular genetic testing services has gained widespread acceptance and utilization based on both positive clinical and financial performance data; thus, our members have substantial experience with the processes and obstacles associated with coverage and reimbursement for infectious disease molecular testing. In addition, as the scope of the SACGHS includes "exploration of the use of genetics in bioterrorism," the ASM has a significant

1752 N Street, NW – Washington, DC 20036
tel: 202-942-9209 – fax: 202-942-9335 – email: publicaffairs@asmusa.org

interest in ensuring that reasonable coverage and reimbursement decisions are made with regard to new genetic technologies used in Sentinel and Laboratory Response Network laboratories for both agents of bioterrorism as well as for naturally occurring emerging infectious diseases of significant concern. Further, it is expected that genetic technologies will continue to play an expanding role in laboratory evaluation of infectious diseases, and coverage and reimbursement in this area is of equal importance.

With regard to the specific potential recommendations described in the draft report:

Recommendation #1: ASM concurs that a set of principles should be developed to guide coverage decision making for genetic tests. The Negotiated Rulemaking Committee for Clinical Laboratory Diagnostic Tests that was convened in 1998 as mandated by the Balanced Budget Act of 1997, provides an excellent model for such a process. Under Negotiated Rulemaking, 23 National Coverage Decisions (NCDs) were developed through a consensus process involving 18 professional group "stakeholders" who were charged to systematically evaluate available evidence for or against the medical necessity of coverage under certain medical conditions for specific laboratory procedures. While many genetic tests are inherently more complex than those evaluated for NCD development, a similar consensus process requiring evaluation of evidence is strongly recommended. However, it is of note that ASM co-chaired the Infectious Disease Workgroup which developed two NCDs that described coverage conditions for HIV molecular testing for both diagnosis and prognosis.

In particular, there should be a clarification of the relationship, if any, between FDA clearance or approval status and eligibility for coverage reimbursement for in vitro diagnostics designated as Research Use Only or Investigational Use Only. In addition, for those genetic tests that are described as "homebrew" or that use "Analyte Specific Reagents" and therefore are subject only to the Clinical Laboratory Improvement Amendments (CLIA) to determine eligibility for reimbursement, it is strongly recommended that criteria be established for the validation of assays to ensure both analytical and clinical validity, such as those found in the guidelines for molecular testing published by the Clinical and Laboratory Standards Institute (CLSI/formerly NCCLS).

Recommendation #2: ASM concurs that genetic tests and services must be considered specifically with respect to the benefits and clinical utility they can offer the populations for which they are intended. Further, validation of test performance must occur in the population the test is intended for use, as described above.

Recommendation #3: ASM concurs with SACGHS's recommendation that the Secretary encourage the Centers for Medicare and Medicaid Services (CMS) to implement Section 731 of the Medicare Modernization Act of 2003, which requires the development of a plan to evaluate Local Coverage Decisions (LCD) for national adoption and to evaluate Local Coverage Decisions with the intent of achieving greater standardization and consistency. For example, TrailBlazer Health Enterprises, LLC developed a molecular infectious disease LCD in 2004 with significant input from professional societies including ASM, which provided documentation of evidence-based studies. The LCD has been very well received by the medical and scientific community, and a streamlined process by which this LCD could be adopted nationally would

guarantee beneficiary access to these genetic testing services when medically necessary in a shorter timeframe.

Recommendation #4: It is clear that many genetic tests and services providing predictive or predispositional data will ultimately prove to be cost effective in managing healthcare resources. It will be essential that federally funded programs like Medicare allow for payment of these services that under current statutory interpretation would be considered "screening" and therefore "not reasonable or necessary" for coverage. This is currently an issue with regard to infectious disease testing as both the American College of Obstetrics and Gynecology and the American Cancer Society have endorsed the "DNA with PAP" (i.e. a Papanicolaou stain performed on a liquid cervical cytology sample concurrently with a Human papillomavirus DNA virus high risk type molecular test) as an alternative to potentially reduce the frequency of testing required in women who have negative results with both tests. To realize the financial benefits of genetic tests, coverage of such services will be necessary and we concur that in select situations, Medicare coverage should be considered.

Recommendation #5: ASM concurs that HHS should broadly disseminate information serving as the basis for coverage decision making. The process already in place since 2001 for the development of new NCDs, including review by the Medicare Coverage Advisory Committee (MCAC) as well as other existing technology assessment groups, provides a useful resource for obtaining such information for dissemination. In addition, during the process of establishing new CPT-4 codes, documentation is generally submitted to the American Medical Association and to the Pathology Coding Caucus which would not only describe the technology for a new genetic test or service, but would also provide data on the clinical utility and utilization of the assay which, with permission of the AMA, could also be disseminated for use in coverage decision making. In short, much data currently exists that should be more openly shared in development of Medicare and other payer decisions.

Recommendation #6: The Institute of Medicine Report on Medicare Laboratory Payment Policy clearly established that the current National Limitation Amount (NLA) is not relevant to present day laboratory practice, particularly for many emerging technologies. Not only are reimbursement amounts lower than the actual costs of performing the tests, but the current coding system fails to take into account methodological differences that may relate to costs (e.g. "real-time PCR" is not separately distinguished) and in fact, these differences may relate to clinical and financial performance as more data are obtained and evaluated. In addition, there are illogical differences in reimbursement for tests costing roughly an equivalent amount to perform. For example, the NLA for the HIV viral load assay is priced at 2X that of the HCV viral load assay, when in fact, the higher amount is inadequate to cover costs for either. Inherent reasonable authority, when activated, is one avenue to adjust reimbursement to be more reasonable; however, a complete re-evaluation may be necessary to introduce ration and logic into the reimbursement process for genetic services.

Recommendation #7: ASM strongly endorses the recognition of qualified, Board-certified, non-physician providers as valuable and critical members of the healthcare team

by allowing coding for and direct billing for services provided directly by those providers using an assigned National Provider Identifier.

In the case of genetic counselors, ASM endorses the draft recommendation for direct billing of genetic counseling services using an appropriate set of well-defined CPT-4 codes. However, ASM also strongly recommends that the SACGHS consider that other Board-certified clinical laboratory scientists make invaluable contributions in the interpretation of genetic tests and services for which CPT-4 codes currently exist, and for which they are currently unable to directly bill. For example, CPT-4 code 83912 for interpretation of molecular diagnostic tests is reimbursed as a physician fee schedule item when an interpretation is performed by a pathologist, but when interpreted by a doctoral level Board-certified clinical laboratory scientist, no reimbursement for the same service is allowable. For interpretation of complex infectious disease molecular diagnostics other than simple qualitative or quantitative assays (e.g. genotyping assays), no interpretation codes exist. In fact, this concept extends far beyond the genetic test arena, but the disparity is readily apparent here. It should be noted that CLIA regulations recognize individuals holding board certification by the American Board of Medical Microbiology (ABMM) and the American Board of Medical Laboratory Immunology (ABMLI) in the categories of Laboratory Director and Clinical Consultant.

Recommendation #8: ASM strongly concurs that HHS should partner with other agencies and organizations to develop case studies and practice models to demonstrate the relevance of genetic tests and services. In fact, ASM has many active educational programs that use a case study design to demonstrate the relevance of infectious disease diagnostics, diagnostic immunology, and molecular diagnostics. ASM would be pleased to partner with HHS to support such educational objectives.

Recommendation #9: ASM strongly supports the use of HHS resources to increase availability of reliable information for informed decision making by healthcare providers and healthcare consumers. Direct-to-consumer marketing as a trend will likely continue and it is of paramount importance that reliable sources of information be promoted. Again, HPV provides an example from infectious diseases where the sole manufacturer of the HPV molecular test kit has taken a very aggressive approach to advertising its product in a number of popular venues, emphasizing the endorsement in ACOG and ACS practice guidelines. In response, HHS has recently (March 2005) issued a "Dear Colleague" letter clarifying potential points of confusion. In the future, it will be increasingly necessary to remain aware of such marketing campaigns and both reassure and educate consumers and healthcare providers when conflicting information is available. ASM stands ready to serve as a resource in any matters of mutual interest.

In summary, ASM appreciates the opportunity to provide comments on the SACGHS Draft Report on Coverage and Reimbursement of Genetic Tests and Services. While our members have significant interest in current matters pertaining to coverage and reimbursement for molecular diagnostics for infectious diseases and a number of other applications including cancer diagnostics and pharmacogenomics, we anticipate an even greater interest in future years. Not only is there a greater appreciation of the role of the host in the susceptibility to infectious diseases and in determination of the ultimate outcome in the internal battle in an infection, but there is increasing recognition of the

role of microorganisms as triggers of many illnesses here-to-fore considered chronic for which genetic tests may play a vital role in analysis (Microbial Triggers of Chronic Human Illness, American Academy of Microbiology, 2005). Further, advances in microarray technology will yield information on the presence of both known and previously unrecognized microbial agents which will not only be diagnostically useful, but may also raise ethical concerns regarding long term implications for medical and economic well-being of individual patients. This will be particularly true for viruses, which are etiologically associated with malignancy. Therefore, coverage and reimbursement will continue to present challenges in provision of laboratory services, and ASM stands ready to assist SACGHS in any way possible.

Sincerely,

Alice Weissfeld

Alice Weissfeld, Ph.D.
Chair, Committee on Professional Affairs
ASM Public and Scientific Affairs Board

THE AMERICAN SOCIETY OF HUMAN GENETICS

9650 Rockville Pike • Bethesda, MD 20814-3998 • 301-634-7300 • 1-866-HUMGENE • fax: 301-634-7079 • e-mail: society@ashg.org • http://www.ashg.org/

April 29, 2005

Secretary's Advisory Committee on
Genetics, Health, and Society
Reed V. Tuckson, M.D., Chair
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Dr. Tuckson:

Thank you for the opportunity to comment on the draft report; our comments follow this letter. We appreciate the effort that went into preparation of "Coverage and Reimbursement of Genetic Tests and Services."

We will continue to support the efforts of SACGHS in any way we can.

Sincerely,

Peter Byers

Peter H. Byers, M.D.
President
The American Society of Human Genetics

Response to: **The Secretary's Advisory Committee on Genetics, Health, and Society draft report, *Coverage and Reimbursement of Genetic Tests and Services***

By the: **American Society of Human Genetics**
9650 Rockville Pike
Bethesda, MD 20814-3998
(301) 634-7300; society@ashg.org.

Date: **April 29, 2005**

The American Society of Human Genetics (ASHG) commends the Secretary's Advisory Committee on Genetics, Health, and Society on their thoughtful discussions and resulting Draft report on "Coverage and Reimbursement of Genetic Tests and Services". ASHG is the primary professional membership organization for 8000 genetics researchers, clinicians, counselors, laboratorians, and trainees. ASHG concurs with SACGHS that coverage and reimbursement are critical to ensuring access to genetic testing and services, and that substantial barriers and unmet data needs currently exist. While the principal areas of focus for ASHG include research and education, so many of our members' activities include genetic services or are influenced by the clinical milieu, we deemed it important that the Society make some general comments about the draft SACGHS report.

ASHG concurs with the initial statement that the fear or concern of genetic discrimination may cause underutilization of genetic tests even if the financial barriers were removed. Our members have observed such behavior in many circumstances. Therefore, our Society is committed to and continues to work with other partners to see the rapid passage of HR 1227 by the House of Representatives in the 109th Congress.

The American Society of Human Genetics would not disagree with any of the potential recommendations suggested by the SACGHS in the report. We support the concepts of utilizing genetic tests in a preventive strategy health care model, and advocate for the comprehensive consideration of the benefits associated with prevention and pre-symptomatic intervention for patients predisposed to disease.

While it is outside our specific purview to recommend or endorse specific strategies, we believe that it is reasonable to pursue coverage by Medicare for preventive services, including predispositional genetic tests and services that meet evidence standards. ASHG currently supports and participates in a few family history projects that aim to raise awareness about the importance of family medical history in the accurate assessment of an individual's risk to a variety of diseases. We therefore support the SACGHS recommendation to include family history for purposes of establishing that a genetic test is warranted.

Genetic counseling has long been established to be an essential component of the appropriate use and integration of genetic tests and services into comprehensive medical care. As these services, adequately provided, are time and information intensive as compared to many other medical services, it is critical that the CPT E&M codes and their associated values are adequate. Reimbursement under prolonged service codes may be necessary. The genetics community believes strongly in the capabilities of certified non-physician genetic counselors, and supports the appropriate payment of these highly qualified health care professionals for their services.

Because genetic technologies are envisioned to continue to shift health care paradigms, it is critical that training and education of genetic specialists be supported. In addition, genetics content must be infused into all health care and medical professional training so that new information arising from genetic research may be translated into improved health care practices. The genetics community is working hard to achieve these goals as we embark on a new era of personalized medicine that will allow early recognition of risk and intervention to prevent, delay, or minimize adverse health outcomes. ASHG urges SACGHS to continue their advisement of the Secretary to embrace and promote activities that will permit us to realize the promise of genomic and genetic medicine.

America's Health Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.net

May 6, 2005

Suzanne Goodwin
Secretary's Advisory Committee on Genetics,
Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Via e-mail: goodwins@od.nih.gov

Re: Draft Report on Coverage and Reimbursement of Genetic Tests and Services

Dear Ms. Goodwin:

America's Health Insurance Plans (AHIP) appreciates the opportunity to provide comments regarding the Advisory Committee's April 2005 Draft Report, *Coverage and Reimbursement of Genetic Tests and Services*. AHIP is the national trade association representing the private sector in health care and our nearly 1,300 member companies provide health, long-term care, dental, vision, disability and supplemental coverage to more than 200 million Americans.

AHIP believes genetic information can be a key component for patients and their health care providers in making informed health care decisions. Health insurance plans play an important role in promoting the appropriate use of genetic tests by encouraging evidence-based counseling and testing, supporting consumer education and patient awareness, and using genetic test results to enhance preventive screening and disease management.

We have outlined specific comments regarding the draft report in the attached discussion paper. We would also like to share with the Advisory Committee the following general observations about the draft report.

Getting Access to Genetic Tests and Services

The report starts with a general conclusion that "problems with coverage and reimbursement are limiting accessibility and integration [of genetic tests and services] into the health care system" (draft report, page 9). We are not aware of testimony or other information presented to the Advisory Committee during its deliberations that

indicates there is a widespread problem with patients having access to medically appropriate genetic tests and services.

In addition, while concerns with reimbursement were discussed, the testimony presented to the Advisory Committee identified a number of other issues that may impact access to genetic tests and services – inadequate CPT codes, lack of provider identifiers for genetic counselors, public perceptions about possible misuse of genetic test results, genetic test patent disputes, limited training and knowledge on the part of primary care physicians, and shortages of trained genetic clinicians. These additional issues should be highlighted in the report.

We believe the report should meet its two objectives of describing the current state of coverage and reimbursement for genetic tests and making recommendations to improve access to genetics health care and services rather than making broad statements without citations or supporting documentation.

Protections Against Misuse of Genetic Information

We also recommend that the report describe existing federal and state protections for consumers which assure that an individual's genetic information is used responsibly. As noted in AHIP's testimony to the committee, federal law (the Health Insurance Portability and Accountability Act and the Employee Retirement and Income Security Act) and many states specifically prohibit health insurance plans and employer group plans from using genetic information to deny insurance coverage or to establish premiums for individuals. In addition, federal and state laws restrict employers and health insurance plans from using genetic information without the individual's authorization except for purposes of treatment, payment for services, or health care operations such as disease management.

Promotion and Use of Genetic Tests and Services

We suggest the report include information regarding health insurance plan initiatives to provide members with information about covered services for genetic tests, disease management programs, and to improve patient awareness and screening. AHIP's testimony to the Advisory Committee and the testimony of other representatives outlined a number of efforts by health insurance plans to educate health care providers and their patients about uses of genetic information and to encourage appropriate genetic testing.

AHIP commends the Secretary's Advisory Committee on Genetics, Health, and Society for its work to highlight the impact of genetics and to identify challenges to the integration of genetics into health care. We look forward to continuing to work with the committee as it goes forward with its deliberations.

Please feel free to contact me if you have any questions.

Sincerely,

Diana C. Dennett
Executive Vice President

Attachment

Attachment A

AHIP Comments
Draft Report on Coverage of Genetic Tests and Services
Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)
(May 5, 2005)

The following are comments on behalf of America's Health Insurance Plans in response to the Draft Report, *Coverage and Reimbursement of Genetic Tests and Services*. Please note that the page numbers refer to the text of the on-line version of the draft report.

- In the box on page 11, a statement is made that current law prohibiting misuse of genetic information is "inadequate." The report should explain that current federal law (ERISA and HIPAA) and the laws in most states specifically prohibit the use of genetic information to make health insurance coverage and rating decisions in the group market. In addition, although most states will allow underwriting based on medical conditions to protect the viability of the individual health insurance market, health insurers do not request pre-symptomatic genetic test results from applicants seeking coverage and do not use such genetic information in the underwriting process. An Appendix detailing pertinent federal and state laws and regulations (HIPAA and state specific examples) may be helpful.

- The box on page 11 states that "health insurance organizations and groups representing employers are on record stating that they will not use genetic information when making health insurance and employment decisions and many of them support legislation in this area." We believe this statement does not reflect AHIP's testimony which was that HIPAA prohibits group health insurance plans from using genetic information to refuse to cover employees or family members; refuse to renew coverage; charge employees and family members higher premiums; impose pre-existing condition waiting periods; or cancel coverage. In addition, our testimony stated that health insurers in the individual market do not ask people seeking coverage to provide presymptomatic genetic test results; and do not use genetic information in the under writing process; and once a policy is issued it cannot be cancelled for any health-related reasons including genetic predispositon to disease. We recommend that the statement be revised to reflect actual practice in the market.

- The section addressing coverage issues beginning on page 19 should explain that health insurance contracts include information about covered benefits and services. Health insurance purchasers (employers and individuals) receive written information that describes the services covered, how coverage decisions are made, as well as any review process that can apply if an unfavorable decision is made that affects a covered member. Federal and state laws require health insurance plans to provide individuals with information about covered benefits and services when they are covered by a health plan.

- On page 20, the report states that "private health insurance plans make exceptions to their policies on a case-by-case basis." It is more accurate to say that, where pre-authorization is required; coverage decisions are based on the specific facts of an individual's situation and the terms of the insurance agreement.

- On page 20, the discussion of health insurance plan coverage policies should be clarified by adding a discussion that, in general, health insurance plans do not make such policies publicly available because they are proprietary. If a claim for benefits is submitted and subsequently denied, federal and state law and accreditation standards require health insurance plans to provide the individual or health care provider with an explanation of the reason for the denial, including any policy or criteria upon which the decision is based.

- On page 26, the recommendation directs the Secretary of HHS to task a body with developing a set of principles for coverage decisions for genetic tests. We believe that this group should follow the same model as that used by the U.S. Preventive Services Task Force by reviewing cost-effectiveness studies of genetic tests and services -- the Task Force may, in fact, be the appropriate group to carry out this function).

- The report, in the box on page 27, appears to recommend that private health insurance plans do not necessarily need to follow best scientific evidence in making coverage decisions. We believe that both public and private payers should follow best scientific evidence in this regard as noted in the committee's recommendation earlier in the report.

- On page 27, the report states that the private market often follows suit if Medicare decides to cover a service or test. It would be more appropriate to say that public and private payers may update policies and coverage guidelines when a test for a genetic condition when it is based on sound scientific evidence and has been shown to improve clinical outcomes.

- On page 28, the discussion of local coverage determinations should be revised to reflect that Medicare coverage policy decisions will be made by 23 Medicare Administrative Contractors (and not 36 "local contractors").

- The recommendation on page 32 requests CMS guidance regarding the circumstances under which "personal history" could include family history of a particular disease. The recommendation would establish genetic test as reasonable and necessary and therefore covered by Medicare. As noted in the draft report, however, "family history of disease does not meet Medicare's reasonable and necessary criterion" and, as a result, CMS is unable to offer such clarifying guidance in the absence of statutory authority.

- On page 36, there is a statement that (based on anecdotal information) current CPT codes are inadequate for genetic tests. There should be some cited authority for this

statement and the American Medical Association's CPT Editorial Panel, which is responsible for maintaining the CPT coding system, should be involved for input and review. Specific examples in this section would be helpful to the reader to understand the issue and its application to a real-life situation.

- There is a discussion on page 42 regarding the Healthcare Common Procedural Coding System (HCPCS) and the work of the HCPC National Panel to make decisions about additions or revisions to the codes. This HCPC National Panel is no longer in existence and CMS has revised its procedures for making these code decisions. AHIP is not part of the decision making process.

- When discussing claims on page 44, the report focuses on billing procedures and coverage decisions. The reader should also know that a multitude of factors can influence whether a claim is paid (e.g., provider contracted negotiated rates, whether a provider complies with timeframes for claims submissions, etc.).

- The proposed recommendation on page 45 states that payment rates for genetic tests are lower than the cost of performing the test. The testimony regarding reimbursement for genetic tests and services primarily discussed payment by a state Medicaid program. The recommendation should be specifically directed at reimbursements for the Medicaid program.

- The discussion about billing practices for private insurers listed on page 51 does not give the reader a sense of other factors that determine whether a claim will be paid or denied (e.g., contract terms, provider compliance with claims submission timeframes, lack of required documentation, etc.).

- One page 52, a recommendation is made that qualified health providers should be allowed to bill directly for genetic counseling services. This recommendation will require Congressional action because the counselors would be providing a service that is not currently covered under Medicare.

9650 Rockville Pike
Bethesda, Maryland 20814-3993

Tel (301) 634-7939
Fax (301) 634-7990
www.amp.org

Reed Tuckson, M.D., Chair
c/o Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892
Email goodwins@od.nih.gov
Fax 301-496-9839

May 6, 2005

Comments on the Draft Coverage and Reimbursement

Dear Dr. Tuckson and Members of the SACGHS Committee,

The Association for Molecular Pathology (AMP) thanks the committee for the opportunity to provide comments on the draft report, "Coverage and Reimbursement of Genetic Tests and Services." First and foremost, AMP applauds the committee on the thoroughness and thoughtfulness of the report. Such a complete review and assessment of the issues related to the coverage and reimbursement of genetic services is remarkable and highly valuable to the healthcare community.

The Association for Molecular Pathology is an international, not-for-profit educational society representing over twelve hundred physicians, doctoral scientists, medical technologists and professionals who perform and support molecular genetic testing as well as other tests based on nucleic acid technology. The AMP membership is from academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the *in vitro* diagnostic industry. In this capacity, AMP members are involved in every aspect of genetic testing: performance and interpretation of genetic tests, basic and translational genetic research and genetic education. For the last several years AMP has provided national leadership to advance the safe and effective use of molecular genetic testing in health care.

AMP's comments will focus on three major points, Review of the Molecular CPT Codes by CMS, the Definition of Genetics Tests, and Coverage and Reimbursement for Genetic Counseling and Medical Genetics Services, followed by more specific points on items throughout the draft report.

Recommendation to Review of Molecular CPT Code Reimbursement

AMP strongly supports the proposal in the Coverage and Reimbursement document to request CMS to review and revise reimbursement for molecular CPT codes. At the March 2004 SACGHS meeting, Dr. Andrea Ferreira-Gonzalez, as an AMP officer, presented that national and local reimbursement levels for the molecular CPT codes are inadequate to cover the cost of performing genetic tests. As we advance irreversibly toward molecular medicine as standard of care, genetic tests will play an increasingly prominent role in disease diagnosis, prognosis and management. As the number of available genetic tests and their use in routine diagnostics grows, laboratories will not be able to continue absorbing the losses associated with genetic testing, as they do today. AMP expends extensive effort and resources to urge CMS to ameliorate the current state of insufficient reimbursement, which threatens to restrict access to these important tests, with concomitant negative impact on patient care. We strongly support the SACGHS recommendation for CMS to review and revise reimbursement for molecular CPT codes. AMP, through its

resources and knowledge of this subject stands ready to assist CMS in carrying out this recommendation. While this effort will assist in the short term with the inadequacy of reimbursement for molecular tests, AMP will continue to work with other professional groups to look more globally at the adequacy of the current molecular coding system, addressing issues such as the level of automation of testing, the volume of testing and the ability to represent in CPT codes the testing being performed. We hope this process will allow proposal of more global revisions to coding for this high growth area of Clinical Laboratory Medicine. We ask that these groups be given the opportunity to bring future proposals to SACGHS, for your edification and for potential support.

The Definition of a Genetic Test

AMP supports the latest revision of the section "What are genetic/genomic tests and technologies?" This description begins to refine the issue that the term "genetic/genomic tests" has different meanings in different settings. The fact that this was necessary demonstrates that precise definitions need to be formulated and adhered to, and that it is likely that we will need thoughtful categorization of different kinds of genetic testing. One specific concern is the inclusion of pharmacogenetics testing in this discussion, since this testing identifies allelic variants that are not associated with disease, but only affect drug metabolism. Only in the presence of an external challenge (drug) will health risks be apparent

Coverage and Reimbursement for Genetic Counseling and Medical Genetics Services

AMP members performing genetic tests work closely with genetic counselors and medical geneticists. Medical geneticists and genetic counselors provide information to patients and their families about the specific genetic disease, genetic testing options, the meaning of test results and various additional testing and treatment options. These types of genetic services are time intensive and are not adequately reimbursed at this time. AMP strongly supports all the recommendations regarding coverage and reimbursement for genetic counseling and medical genetics services.

Specific Points

Page 22. In focusing on people 65 and older, while the clinical validity may be different for this population (based on age of onset, etc), the analytical validity for inherited disease tests remains the same regardless of age.

Page 24. Please clarify the term "Prevalence of the gene variant." Does this mean disease prevalence, that would drive the ordering of the test, or the common genetic variant(s) seen in the population or all possible variants?

Page 40. The new genetic modifiers are raising more questions than they answer. If the purpose of the molecular CPT Modifier Codes is to clarify the type and purpose of testing, then one modifier code can still apply to several different levels of testing for the same disease. For example, in cystic fibrosis (CF), testing can be for one mutation only (when documented that this is the familial mutation), for 23-80 mutations for a CF panel, and for full gene analysis for an affected individual when two mutations are not detected by the panel or for atypical CF patients. Will these levels of testing be misunderstood when using the CF modifier?

Page 46. Education of insurance companies is a key factor in greater use and acceptance of genetic tests in clinical practice. Several years ago, Blue Cross/Blue Shield of Utah had a policy of not covering any genetic tests, since these tests were considered research. Through education by physicians, laboratorians and genetic counselors, Blue Cross/Blue Shield of Utah has reviewed its policy and will be including genetic tests, for at least a number of common disorders, in 2006.

Page 47. AMP asks that SACGHS give full consideration to the negative impact of exclusive licensing and enforcement practices for gene patents on the future of genetic testing.

We understand that SACGHS has set this as a high priority but has decided to wait for the National Academy of Sciences study of intellectual property related to genomics and proteomics. We urge you to promptly set this as an agenda for the SACGHS as soon as the report is available.

Page 47. The cost of testing is directly related to test volumes. The ability to "batch" samples decreases the cost dramatically, while rare testing performed on one specimen at a time are very expensive.

On behalf of AMP, I thank you for the opportunity to comment on the draft report on Coverage and Reimbursement of Genetic Tests and Services. AMP remains available to the SACGHS to assist with or provide information for your thoughtful deliberations and important work.

Sincerely,

Mark A Lovell, MD

Mark A. Lovell, M.D.
President, Association for Molecular Pathology

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

Allan M. Korn, M.D. FACP
Senior Vice President
Clinical Affairs
Chief Medical Officer

225 North Michigan Avenue
Chicago, Illinois 60601-7680
312.297.6840
Fax 312.297.5726
allan.korn@bcbsa.com

May 6, 2005

Reed Tuckson, M.D.
Chair
Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)

Via e-mail

Dear Dr. Tuckson:

Thank you for your letter inviting comments on the SACGHS draft report: *Coverage and Reimbursement of Genetic Tests and Services.* I am pleased to respond on behalf of the Blue Cross and Blue Shield Association (BCBSA), an association of 40 independent Blue Cross and Blue Shield Plans providing health benefits to over 92 million Americans, almost one in three.

The BCBSA commends the members and staff of the SACGHS for a thorough analysis of the current state of coverage and reimbursement of genetic tests and services and for thoughtful recommendations on how coverage mechanisms could be improved. The comments provided below address modest differences in perception of certain factors, processes, and barriers to appropriate coverage of genetic tests and services. In the main, we agree with the issues identified and direction of the draft recommendations.

The Introduction to the report identifies a number of barriers to coverage and payment of genetic services and tests. These include: "the novelty and predictive nature of many genetic tests, the limited availability of data to support evidence-based coverage decisions, lack of a process for identifying and addressing gaps in evidence, and limitations in Medicare statute and policies" (p. 9) An omission from this list contributes directly to the limited availability of data and gaps in evidence. That omission is the lack of appropriate FDA regulation of market entry of genetic tests developed by laboratories (or home-brew tests). Most new genetic tests are introduced as home-brew products. They are permitted to enter the market without evidence of safety or effectiveness. Genetic test kits or chips that are required to be approved by the FDA in the same manner as devices are held to a much less rigorous standard than new drugs. Data demonstrating an impact on clinical outcomes meaningful to patients are not required by the device approval process. The absence of regulations requiring demonstration of clinical validity and utility prior to market

introduction of new genetic test relieves test developers of the need to accumulate data that could support evidence-based coverage decisions.

The focus throughout the report on the importance of evidence-based coverage is welcome, as is the stated awareness of the limited and finite resources in our health care system in which 43 million citizens lack insurance benefits at any point in time. We strongly support programs and processes of test development and validation that go beyond establishing test performance characteristics and disease association and that link the use of genetic tests to clearly defined medical outcomes. Such information is largely lacking today, making it difficult to establish clinical utility.

We have additional, specific comments on the evidence-based coverage process as described in the report. The report states that genetic tests and services should be covered when there is "adequate evidence to support their use and reimbursement." (p. 10). The report goes on to say that other considerations, such as benefits and risks, may also need to be factored into the coverage decision-making process. On page 22, the report indicates that evidence-based decision-making involves assessing existing data on analytical and clinical validity and clinical utility. This clear statement is followed by: "Coverage decision making also involves consideration of other factors such as the test's safety, and effectiveness and the tests risks, cost, and impact on health outcomes." Effectiveness should be encompassed in the concept of clinical validity and safety, risk, and impact on health outcomes are all critical to an assessment of clinical utility. Cost is not inherent to the notions of validity and utility, but effectiveness and risk and benefit clearly are. The inset box "Considerations in Making Coverage Decisions for New Technologies" also asks: "Is it experimental" (what does "experimental" mean in this context?), "Does the public approve of its use?" (How would we know and why should this be a factor?) I) and "Do other health care payers already cover it?" (if the data demonstrate the test has clinical validity and utility, each payer should reach a coverage determination independent of the actions of other payers).

The issue of "informational utility" of genetic tests is broached a number of times in the report. We appreciate citation of the BCBSA TEC criteria in the body of the report and note the key criterion of improvement of net health outcomes. We cannot agree that a sense of personal well-being (p. 14) and estate planning constitute meaningful health outcomes in assessing clinical utility of a genetic

test. Tests that identify mutations for which no therapy is available may improve health outcomes by playing a key role in increasing or reducing ongoing disease surveillance. They may also meaningfully contribute to family planning. These are health outcomes. Estate planning is not. Furthermore, negative test results, for certain mutations can confer a false sense of security. Being negative for the BRCA 1 and 2 mutations does not reduce a woman's risk of breast cancer to zero. And while negative test results may confer a sense of well-being, positive test results will have the opposite effect. For conditions that cannot be remedied or prevented, the impact of "bad news" may have no counterbalance.

We recognize the potential value of a set of principles to guide coverage decision-making for genetic tests. We agree that such principles should address the role of cost-effectiveness and clinical versus "informational utility". An ongoing multi-stakeholder group to assess the existing evidence of analytical and clinical validity and clinical utility would also prove invaluable. We agree that EGAPP may be an appropriate body to perform these critical functions.

A number of statements are made in the report about coding that are contrary to our experience. It is true that the 5-digit CPT codes are technique based and do not permit the payer to identify what test is being performed. Payers will not reimburse for services that they cannot identify and which lack all evidence of medical necessity. The 2-digit modifiers adopted by CPT help address this problem. Modifiers adopted by CPT cannot be rejected by health plans under HIPAA. The health plan is not required to cover services identified with the modifier or to pay for the services at a certain level, but the plan may not "deny the claim" because the modifiers are submitted as stated in the Coding Systems section. The V codes within ICD-9-CM also help the health plan identify the test and why it may have been performed. The payment rate is based on the CPT code and V codes are not reimbursed on their own as stated in the report. The Evaluation & Management codes in CPT provide the mechanism for reporting cognitive services. The times given in CPT are guidelines not limits. Prolonged service codes should not be denied out of hand and denials that are issued can be appealed if the provider has appropriately documented the care.

The BCBSA recognizes the importance of appropriate genetic counseling and also recognizes that there is a range of clinicians who may be qualified to provide counseling through training and

experience. We would endorse mechanisms to define appropriate training and to facilitate reimbursement for these important services.

Thank you for the opportunity to comment on this thought-provoking report.

Very truly yours,

Allan M. Korn, MD, FACP
Chief Medical Officer and
Senior Vice President

BOSTON HEALTHCARE

from mind to market®

Boston Healthcare Associates, Inc.
75 Federal Street, 9th Floor
Boston, MA 02110
T: 617. 482. 4004
F: 617. 482. 4005
www.bostonhealthcare.com

May 6, 2005

Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Dear Committee Members:

We write to express our support for the recommendations of the report on Coverage and Reimbursement of Genetic Tests and Services. We are a reimbursement planning consulting firm that works with life sciences industry clients to help them better understand the coverage, coding and payment environment for new technologies, including diagnostics, pharmaceuticals, and devices.

An area of particular interest and expertise of our firm is reimbursement for molecular diagnostics and laboratory services. Many of our clients are engaged in the development and commercialization of novel genetic tests. In general, these innovators are concerned that inadequate payment levels for diagnostic tests may limit future innovation by hampering investment in important medical technologies. Furthermore, our research has consistently shown that imprecise coding descriptors and inadequate payments may also hinder patient access to innovative medical technologies.

We believe this report will highlight and build momentum for real solutions to the reimbursement issues that genetic tests face, now and in the future. As the committee points out, this report will assess what needs to be done to address issues associated with current testing but will also be used to prepare for future genetic / genomic technologies. These tests represent the potential to fundamentally alter disease treatment protocols and present novel and cost-effective ways of delivering preventative care. In light of the importance of this report, we would like to suggest three additional concepts for your consideration:

1) We strongly support the recommendation that the Secretary of Health and Human Services use his "inherent reasonableness" authority to address variations in payment rates for genetic test Current Procedural Terminology (CPT) codes. However, we also urge the committee to go one step further and urge the Secretary to use his authority to address all payment rates for molecular diagnostic genetic tests and call on Congress to end the freeze on payment rates that was included in the Medicare Modernization Act. This freeze has left many labs and vendors to bear the burden of cost for new tests that continue to be demanded by clinicians. In many cases, payment rates for different tests with very different associated costs are linked to a single dollar amount which was determined in the 1980s.

   Currently, the system relies on the ability of laboratories provide more expensive testing at a loss while attempting to recoup losses on higher-volume, less expensive tests. Relying on an equation of payment averages creates a challenging environment for ensuring widespread access to novel tests. It may also create a perverse incentive to provide more less expensive, and potentially less

accurate, testing rather than providing fewer more expensive and effective tests. A further flaw of this model is that it does not work for novel tests that provide significant benefits but will only be performed by a few or a sole-source CLIA certified lab that has the capability to perform the test. These labs will not be able to benefit from, as the report states, the "subsidization of new tests through the overpayment of more established tests."

It is clear that the Secretary and Congress will need to work to change these outdated rate calculations. As the committee correctly point out, making changes to the Medicare payment rates will be relevant for both public and private payors because private plans often follow their evaluation. Not doing so may indeed stifle investment and innovation in this important area.

2) Further, we also urge the committee to encourage the Secretary that if he does take action using his "inherent reasonableness" authority that he does so through an open and comprehensive process. Allowing public input will ensure that the Secretary will have accurate information about the novel features and capabilities of new and better developed tests. The complex nature of many of these tests requires input from those who best understand the tests. This includes not just from the major laboratory groups but also smaller molecular diagnostic start-up companies that are at the forefront of genetic testing development.

3) Finally, we urge the committee to recommend a comprehensive re-evaluation of the coding system for molecular diagnostics. We agree that the addition of gene-specific modifiers was a positive step forward in helping laboratories, clinicians, and payers identify which techniques are being used for which tests but more needs to be done as linkages between different genes and diseases are being discovered on a daily basis. Also, with the advent of new testing methodologies that involve looking at many genes simultaneously there is a dire need to reexamine the coding system. The current system was not designed to accommodate the scientific advancements of today's genetic testing environment and it will take a coordinated effort among the Secretary, Centers for Medicare & Medicaid Services (CMS), the American Medical Association (AMA), and the various laboratory stakeholders to resolve this.

Thank you for your time and effort on this important task. We look forward to working with you on development of a comprehensive report.

Regards,

Joseph V. Ferrara
Executive Vice-President

May 2, 2005

SACGHS
NIH Office of Biotechnology Activities
6705 Rockledge Dr., Ste. 750
Bethesda, MD 20892

Dear SACGHS:

We are writing on behalf of the Women's Institute at Carolinas Medical Center in Charlotte, NC to support the recommendations made in the Draft Report of *Coverage and Reimbursement of Genetic Tests and Services* and to recommend a change in the recommendation on Billing and Reimbursement of Genetic Counseling services We are a team of six perinatologists and six genetic counselors who provide preconceptional and prenatal genetic services in a high volume out-patient clinic hospital-based teaching facility.

With respect to recommendations under *Billing and Reimbursement of Genetic Counseling Services,* we request that you recommend to the Secretary of HHS that genetic counselors certified by the American Board of Genetic Counseling (ABGC) be clearly identified and recognized as qualified providers who should have the ability to bill independently. Enabling ABGC certified genetic counselors to bill independently is an important step towards increasing patient access to genetic services.

The number of genetic tests available to couples considering pregnancy and those who are pregnant continues to increase at a rapid rate. ABGC certified genetic counselors are uniquely qualified to provide the detailed risk assessment and education about genetic tests that are medically indicated for each individual couple. In addition, ABGC certified genetic counselors are uniquely qualified to provide post-test education regarding the significance of genetic results so that couples can make informed reproductive decisions. In many cases, the time it takes to provide this information in a thorough manner can range from 30 minutes to more than 2 hours, which is time that physicians typically do not have to devote on a per patient basis. In the absence of access to qualified genetic counselors, there is potential for couples to be poorly advised of their testing options, for genetic tests to be ordered without appropriate indication, and for inaccurate information to be provided regarding the results of genetic tests. Furthermore, there is potential for limited healthcare dollars to be spent on non-indicated genetic tests in lieu of quality genetic counseling that can both optimize the use of those dollars while preventing unnecessary expenditures.

The following examples illustrate the above points.

1. A couple was referred to us after experiencing their second miscarriage. Chromosome analysis was performed on material from the second miscarriage and a trisomy 21 (Down syndrome) chromosome constitution was identified. The couple should have been provided access to us at that point to discuss these results.

However, the obstetrician drew blood from the couple for additional chromosome studies to confirm that the trisomy 21 was not hereditary. Had the couple been seen by us, we would have counseled them that trisomy 21 is not hereditary so there was no indication to perform chromosome analysis of them. Consequently, two very expensive tests would have been avoided.

2. A local obstetrician contacted us requesting the name of a laboratory to which she could send the blood of a pregnant woman who has a family history of hemophilia, an inherited blood clotting disorder. The patient desired genetic testing to determine if she was at increased risk for having a child affected with hemophilia. The patient's insurance policy would not cover the cost of genetic counseling so the obstetrician told the patient that she would draw her blood and send it for testing. Genetic testing for hemophilia can be performed by different methods and each testing method provides different information regarding an individual's genetic risk. In addition, not all laboratories utilize the same testing methodology. Had the patient been seen by us, a thorough family history risk assessment would have been conducted to determine if testing was indicated, a determination would have been made regarding which testing method(s) were most appropriate to address the patient's particular risk, and education would have provided to ensure that the patient had full understanding of the implications and limitations of the test results with respect to the health of her unborn baby.

3. A couple gave birth to a son affected with the classic form of congenital adrenal hyperplasia (CAH), an inherited disorder that leads to ambiguous genitalia in affected females and adrenal crisis in both sexes. The couple's son was followed by an endocrinologist, but the family never received genetic counseling. The couple became pregnant with their second child who had a 25% risk to also be affected with CAH. The couple was told by the endocrinologist that no special prenatal care was needed until 18-20 weeks of pregnancy. In fact, it is recommended that all pregnant women at risk for having a child affected with CAH be treated with dexamethasone beginning at 6 weeks gestation to prevent ambiguous genitalia in affected females. The couple was offered first trimester prenatal testing to determine the sex of the fetus, but they believed it was not indicated based on the information they had received from the endocrinologist. The couple was eventually seen by us at 19 weeks of pregnancy and ultrasound revealed the fetus to be female with ambiguous genitalia. Subsequent genetic testing confirmed that the fetus was affected with CAH. This couple's daughter now requires extensive reconstructive surgery of her urogenital system. Appropriate access to genetic counseling prior to conception or at the time of pregnancy confirmation would have prevented this child's urogenital birth defects, the expenditure of healthcare dollars on costly post-natal surgeries, and the emotional trauma experienced by this family.

We support the remainder of the recommendations regarding genetic counseling service coverage and reimbursement, including 1) directing CMS to allow non-physician health professionals who are qualified to provide genetic counseling services to utilize the full range of CPT E&M codes available for genetic counseling services and 2) the assessment of the adequacy of existing CPT E&M codes and their associated relative values with respect to genetic counseling services.

Thank you for the work you are doing in this area and your consideration of our request. If you have questions regarding the work we do at the Women's Institute at Carolinas Medical Center, please feel free to contact us at your convenience at (704) 355-3149.

Sincerely,

Cheryl Dickerson, MS, CGC
Genetic Counselor

Teresa Brady, MS, CGC
Genetic Counselor

Nicole Lasarsky, MS, CGC
Genetic Counselor

Paige Layman, MS
Genetic Counselor

Stephanie Nix, MS
Genetic Counselor

Beth Swing, MS, CGC
Genetic Counselor

Ronald Wade, MD
Medical Director, Women's Institute

Avick Mitra, MD
Director, Maternal Fetal Medicine

Thomas Stubbs, MD
Associate Director, Maternal Fetal Medicine

John Allbert, MD
Associate Director, Maternal Fetal Medicine

Sheri Jenkins, MD
Assistant Director, Maternal Fetal Medicine

Courtney Stephenson, DO
Assistant Director, Maternal Fetal Medicine

College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

Direct Response To:
DIVISION OF GOVERNMENT
AND PROFESSIONAL AFFAIRS
1350 I Street, NW, Suite 590
Washington, DC 20005-3305
202-354-7100 Fax: 202-354-7155
800-392-9994 • http://www.cap.org

May 6, 2005

Reed Tuckson, MD, Chair
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Re: Secretary's Advisory Committee on Genetics, Health, and Society Coverage and Reimbursement of Genetic Tests and Services Draft Report

Dear Dr. Tuckson,

The College of American Pathologists (CAP) is a national medical specialty society representing more than 16,000 pathologists who practice anatomic pathology and laboratory medicine in the United States and Canada. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 laboratories worldwide. College members have extensive expertise in providing laboratory services and serve as inspectors in the accreditation program. In addition, the College provides laboratories with a wide array of proficiency testing and educational programs to assist in improving the laboratory's performance and its positive impact on patient care. We are providing the following comments in response to the Department of Health and Human Services (HHS) Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) Coverage and Reimbursement of Genetic Tests and Services Draft report.

The comments expressed by the College reflect a set of fundamental principles regarding genetic testing and quality laboratory medicine as related to the recommendations outlined in the draft report. The College recognizes the tremendous contribution genetic testing will have on the advancement of health care and its increasingly important role in pathology and laboratory medicine. Pathologists are involved in every aspect of genetic testing, including research and development, administration and interpretation. Pathologists also are responsible for the safe, effective performance of tests, as well as the confidentiality of resulting information, and regularly interact with other relevant disciplines, including genetic counseling, primary health care, public health and clinical laboratory management.

While the College appreciates the effort on behalf of the SACGHS to identify and make recommendations on appropriate coverage of and reimbursement for genetic testing, the recommendations are but the first step to address the sweeping policy changes needed to

allow genetic testing to fulfill its full promise of improved health care. As provided in the report, the College has taken a leadership role in genetic test coverage and reimbursement through its sponsorship of the Genetic Test Coding Workgroup. The Workgroup was responsible for recommending the addition of numeric–alpha modifiers to supplement the existing five-digit CPT laboratory codes used for genetic testing. AMA adopted these modifiers and included them in Appendix I of *CPT 2005*, its annual listing of current CPT codes. While it was realized that the modifiers would not completely capture the human genome, they present a viable solution to the expected growth of molecular genetics in clinical practice over the next decade while the technology and other nomenclature systems mature. In addition, the Pathology Coding Caucus (PCC) was established under the American Medical Association CPT Editorial Panel and the College to provide physician and non-physician stakeholders who are not currently part of the CPT Editorial process the ability to participate in the development and review of CPT code change proposals for pathology and laboratory services. The purpose of the PCC is to foster a greater degree of participation from non-physician stakeholders in the CPT process while maintaining a predictable, systematic process for revising and updating CPT codes.

Building on these initiatives, the College will develop a comprehensive plan to address the need for new genetic and molecular pathology test codes, create mechanisms to engage genetic and molecular pathology organizations on coverage and reimbursement issues and eliminate barriers to full utilization of genetic and molecular pathology services.

Genetic Tests & Services: Challenges to the U.S. Health Care System

SACGHS Recommendation
Genetic/genomic technologies are processes or methods used to analyze human DNA, RNA, genes, chromosomes, proteins, or metabolites that detect mutations, chromosomal changes, karyotypes, phenotypes and/or expression pattern variation. Genetic/genomic technologies are applied to tests for germline, inherited and/or acquired variations in the genome, transcriptome and proteome.

College Comment

The report offers a definition of genetic/genomic tests and technologies and attempts to make the distinction between tests performed using methods to test DNA or RNA, including germline, heritable and acquired somatic variations, and tests to detect proteins and metabolites. The College recommends that the SACGHS adopt a medically precise definition in the report to target those predictive tests that will generate information important enough to warrant counseling patients and their family members as to the risk of disease. The College believes that genetic information relates to information about genes, gene products or inherited characteristics that may derive from an individual or family members that is used for one or more of the following purposes: to predict risk of

developing an inherited condition; diagnose an inherited condition that is currently expressed; identify carriers of inherited conditions; treat inherited conditions; and for genetic counseling for inherited conditions. The use of a broader definition of "genetic" will encompass most laboratory tests that do not warrant genetic education and counseling. The College believes these tests have markedly different implications and concerns from predictive genetic tests, and we believe it would be confusing and unnecessary to include this definition in the report. We would emphasize that the more narrow definition—a test for a germline and/or heritable alteration, and not for somatic variants—should be used in developing public policy related to science, testing oversight and the ethical contexts of genetic testing. We agree with the statement in the report that tests for non-inheritable variations and those predicting response to therapy generally do not raise as many ethical, legal, and social issues for patients and family members as genetic tests for heritable disease.

Furthermore, as the SACGHS moves forward to address other policy areas related to genetic testing, the College would recommend that the Committee carefully consider how genetic testing and technologies are defined on a case-by-case basis.

Coverage

SACGHS Potential Recommendation
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.

College Comment

The College supports the recommendation that the Secretary task a body to develop a set of principles to guide coverage decision making for genetic tests. This recommendation is consistent with the above-mentioned College strategic initiative to broadly address the coverage and reimbursement of genetic testing. Further, the College and other genetic and molecular pathology specialty societies have had discussions with a number of private insurers regarding the coverage and reimbursement of genetic tests. Although important for patient access to these technologies, these discussions have historically been resource-intensive and somewhat unproductive. This report recognizes that, because few private health insurance plans make their coverage policies publicly available, it is difficult to assess which genetic tests and services are covered. This recommendation

would help to bring about efficient and productive interaction with private insurers regarding the coverage of genetic tests.

In addition, the College supports the recommendation that the existing evidence for specific tests be assessed 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. The College recognizes the importance of developing a systematic, evidence-based process for assessing genetic tests in transition from research to practice. The College welcomes the opportunity afforded by the Centers for Disease Control and Prevention (CDC) project on the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) in developing a working group to address genetic medicine issues from this perspective.

Medicare Coverage

SACGHS Potential Recommendation
SACGHS recommends that the Secretary encourage 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.

College Comment

The College agrees with the SACGHS recommendation to allow CMS to implement a provision (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 bring greater consistency in Medicare coverage policy. Molecular pathology and genetic testing are compelling areas of growth in new technology that have significant implications for the practice of pathology and the specialty's ability to provide critical patient care information to patients and physicians. Therefore, the College is very much interested in and keenly aware of the implications of Medicare coverage criteria for patient access to new technology in the clinical laboratory. While the College recognizes the advantages of determining coverage through the existing CMS National Coverage Decision process, the provision in the Medicare Modernization Act provides for potential interaction with CMS in an open process. This represents a significant change over earlier procedures, which in many instances have taken much longer to complete.

SACGHS Potential Recommendation
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.

College Comment

The College agrees with the SACGHS recommendation that preventive services, including predispositional genetic tests and services, should be covered under Medicare. In addition, we agree that CMS should establish appropriate guidance allowing the use of family history of a particular disease for purposes of establishing that a predictive genetic test is "reasonable and necessary" and, therefore, covered under Medicare. It is well documented that knowledge of certain susceptible conditions presents patients the opportunity to seek treatment and consider preventive action. Specific predictive testing for breast and colon cancer, for example, are available to assist patients to determine the risks of developing those particular diseases. The College has previously recommended that CMS should recognize family history for testing coverage of certain diseases under the Medicare program. In response to the College recommendation, CMS recognized that there may be many instances when testing of beneficiaries in the absence of specific signs, symptoms, diagnosis, or exposure to disease is appropriate, and committed to generating an internal request for a national coverage decision addressing the role of family history as a medical justification for a test being reasonable and necessary.

Billing and Reimbursement of Genetic Tests

Medicare Clinical Laboratory Fee Schedule

SACGHS Potential Recommendation
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 CPT codes through its inherent reasonableness authority.

College Comment

The College agrees with the draft report's findings that payment rates for genetic tests on Medicare's Clinical Laboratory Fee Schedule are lower than the costs to provide the tests by laboratories. We also agree that the inherent reasonableness process could be used to temporarily address the discrepancies between cost and payment for genetic tests currently listed on Medicare's clinical laboratory fee schedule. Further, we recommend

that this report to HHS be amended to include specific examples of the costs to laboratories to perform genetic test. Detailed information, including examples of the costs associated with performing several genetic tests, was presented to the committee and should be included in the final report, as CMS will need cost data to address variations in payment rates for genetic test codes through the inherent reasonableness process. Specifically, the following reported costs should be included in the final SACGHS report.

2005-2008 Medicare Clinical Laboratory Fee Schedule
Amounts for Genetic Testing Codes

HCPC	Description	State Median	Range	National Limit	Reported Costs
83890	Molecular isolation or extraction	$ 5.60	$ 3.26-5.60	$ 7.57	$15.60 [1]
83891	Isolation of highly purified nucleic acid	$ 5.60	$ 3.26-5.60	$ 7.57	$24.75 [2]
83892	Enzymatic digestion	$ 5.60	$ 3.26-5.60	$ 7.57	$17.85
83893	Dot/slot blot production	$ 5.60	$ 3.26-5.60	$ 7.57	$5.63
83894	Separation by gel electrophoresis	$ 5.60	$ 3.26-5.60	$ 7.57	$19.25
83896	Nucleic acid probe, each	$ 5.60	$ 3.26-5.60	$ 7.57	$5.45/$76.84 [3]
83897	Nucleic acid transfer (e.g., Southern, Northern)	$ 5.60	$ 3.26-5.60	$ 7.57	$29.85
83898	Amplification, single primer pair, each primer pair	$23.42	$5.37-23.42	$31.65	$34.00/$39.54 [4]
83903	Mutation scanning, single segment, each	$23.42	$5.37-23.42	$31.65	$32.00

[1] Factor V Leiden
[2] Immunoglobulin Gene Rearrangement by PCR
[3] Factor V Leiden/Fragile X Syndrome by Southern Hybridization Analysis
[4] Fragile X Syndrome by PCR/Immunoglobulin Gene Rearrangement by PCR

Royalty Fees

We appreciate the Committee's concern with the potential negative impact of genetic testing licensing agreement royalty fees on the availability of genetic testing services. As medical specialists in the diagnosis of disease, pathologists have a keen interest in ensuring that gene patents do not restrict the ability of physicians to provide quality diagnostic services to the patients they serve. When patents are granted, subsequent exclusive license agreements and excessive licensing fees prevent physicians and laboratories from providing genetic-based diagnostic services. Patients suffer because diagnostic test services are less readily and affordably accessible. Medical education and clinical research are also threatened. Especially troubling is the fact that under patent protection, the understanding of the utility of the test, as well as the underlying disease processes, also becomes proprietary, thereby imposing a profound change in how the profession and the public acquire knowledge about these tests and their applications. As a consequence, costs are higher, patient access to care is limited, quality is jeopardized and training of health care providers is restricted.

Billing and Reimbursement of Genetic Counseling Services

SACGHS Potential Recommendation
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 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 an NPI.

• 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.

College Comment

In this section, the draft identifies the unique qualifications for non-physician genetic counselors, based on their specialized training and certification, and highlights the lack of specific codes for billing genetic counseling services. While the College recognizes the value of genetic counseling services, we do not believe that the potential recommendations are best targeted to address the issues outlined in the draft report.

The draft report states that the lack of specific codes for genetic counseling services can be problematic, due to the nature of these services as compared with regular provider visits, and that only a low-level established patient Evaluation and Management (E&M) CPT code is available for billing purposes. While the report accurately reflects the current obstacles for genetic counselors to utilize E&M CPT codes, a recommendation

focusing on the establishment of new CPT codes to specifically address the unique services performed by genetic counselors would better address this issue. According to the draft report, the American College of Human Genetics previously submitted a proposal for the creation of CPT codes for family history/risk assessment/pedigree analysis. This proposal was tabled, as the CPT Editorial Panel had begun taking steps to revise the E&M codes. Due to the suspension of the effort to revise the E&M codes, the report indicates that this proposal will be resubmitted.

The full range of E&M codes would not be appropriate for genetic counseling services. While current E&M CPT codes include taking a patient's health and family history, these codes recognize seven components, six of which are used in defining the levels of services. These components are: 1) history; 2) examination; 3) medical decision making; 4) counseling; 5) coordination of care; 6) nature of presenting problem; and 7) time. Again, we believe that a recommendation focusing on the establishment of new CPT codes designed to represent the services performed by genetic counselors would better serve the purposes of this report.

The intent of the SACGHS recommendation that CMS should deem all non-physician health providers who are currently permitted to bill directly any health plan—public or private—eligible for an NPI is not clear. As the discussion in this draft regarding provider identifiers states, auxiliary personnel, such as nurses and genetic counselors who are not currently eligible for a UPIN but who are able to bill some health insurance plans directly, will be eligible to receive a National Provider Identifier (NPI) under HIPAA administrative simplification provisions. Therefore, we would recommend the removal of this particular recommendation.

The College understands the challenges that exist to ensure appropriate coverage and reimbursement for genetic testing services and is absolutely committed to that end. We look forward to working with the SACGHS, HHS and its agencies, and other relevant organizations to achieve this goal. We appreciate the opportunity to provide these comments. If you have any questions, please contact Phil Bongiorno (202) 354-7113 or pbongio@cap.org.

Sincerely,

Mary E. Kass, M.D.

Mary E. Kass, MD, FCAP
President

COMMENTS SUBMITTED BY:

GENETIC ALLIANCE

TO THE

SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY

"EXAMING THE ISSUES SURROUNDING THE COVERAGE AND REIMBURSEMENT OF GENETIC TESTS AND SERVICES"

May 6, 2005

The Genetic Alliance Board of Directors appreciates the opportunity to address the Committee regarding the *Coverage and Reimbursement of Genetic Tests and Services* draft report. We would like to applaud the Committee for tackling this complicated and controversial topic, and commend it on a job well done.

An international coalition comprised of more than 600 advocacy, research, and health care organizations that represent over 14 million individuals with genetic conditions and their interests, Genetic Alliance is guided by the conviction that access to health care, education, and employment is essential to all individuals, regardless of genetic inheritance. As such, the issues surrounding the coverage and reimbursement of genetic tests and services are of significant interest to our organization and its members. While we appreciate the thoughtful recommendations outlined by the Committee's report, we must first acknowledge that the effectiveness and impact of all proposals is dependent on the passage and enactment of Genetic Information Nondiscrimination Legislation. Furthermore, adequate education, for both health care professionals and consumers, on the subjects of genetics and genetic testing is essential to ensure appropriate coverage and reimbursement for genetic tests and services.

After examining the recommendations made in the *Coverage and Reimbursement of Genetic Tests and Services* draft report, Genetic Alliance recommends the following additions and clarifications:

- **Allowing qualified health care providers to bill directly for genetic counseling services.**
    - **The Secretary should expeditiously identify an appropriate mechanism for validating the credentials of approved providers and for determining the credentials non-physician health care providers must present to be deemed qualified.**
- **Adding "informational utility" to the criteria—which now includes analytical and clinical validity—used to determine the value and importance of genetic tests.**
- **Ensuring that the use of cost-effectiveness data does not eliminate coverage for services related to rare diseases.**

- **Reducing private insurer's reliance on Medicare and Medicaid decisions related to coverage and reimbursement of genetic tests and services.**
- **Creating an environment in which preventative care is more likely to be covered by insurers.**

Qualified health care providers should be allowed to bill directly for genetic counseling services.

Referring specifically to the potential recommendation on page 52 of the Committee's report that addresses qualified providers of genetic counseling services, Genetic Alliance recommends that the language be revised to read:

> "Qualified health providers—including board certified genetic counselors and advanced practice nurses with the APNG credential provided by the GNCC—should be allowed to bill directly for genetic counseling services. The Secretary should expeditiously identify an appropriate mechanism for validating the credentials of approved providers and determining the credentials and criteria necessary to classify non-physician providers as qualified to provide, and eligible to bill directly for genetic counseling services."

Until genetic specialists are fully integrated into the health care system, medical genetics will not achieve its incredible potential.

Genetic tests and services that have not demonstrated analytical and/or clinical validity must be, at the very least, considered for coverage.

As the Committee's report correctly indicates, genetic tests and services often do not qualify as either analytically or clinically valid. However, these tests should continue to be considered necessary research tests. Furthermore, this report acknowledges the importance of the utility of a test—usually determined by the potential medical interventions—to the coverage decision-making process. However, genetic tests may demonstrate utility that extends beyond the bounds of the traditional medical model. Through discussions with our members, we have become acutely aware that information is critical. Sometimes all a family has is information, knowledge that then becomes a fundamental component in all of their planning processes. In addition, particularly in the case of rare diseases, affected individuals and families who learn about a condition can participate in registries and research, allowing for an improved characterization of that disease and the possible development of medical, psychosocial, and educational interventions.

Cost-effectiveness data, while necessary, must not be overemphasized in the coverage decision-making process.

Though Genetic Alliance recognizes the reality of cost-effectiveness as a criterion for determining coverage, we urge the Committee to stress the importance of providing services to individuals with rare diseases despite the cost. Individuals with rare

conditions represent a community that faces a seemingly infinite stream of challenges; the lack of insurance coverage for testing services is one of the many barriers impeding the maintenance of an individual's health and well-being. Additionally, in order for research to advance, registries and cohorts must be built with accurate data from test results. We know that the study of rare diseases can lead to extraordinary progress in the diagnosis and treatment of common diseases that share a pathway, but this will happen only if we make a concerted effort to encourage research in this area.

Coverage decisions should not be made based on the Medicare program's coverage alone.

While Medicare is the largest health insurance provider in the United States, by definition it excludes a number of segments of the population. That fact notwithstanding, private insurers use coverage decisions made for the Medicare program as guidelines for their own policies. Unfortunately, as the Committee has acknowledged, the result of this behavior is a system that limits coverage of certain tests and services for everyone simply because those tests do not necessarily have significant value for the Medicare population—people age 65 and older, people with certain disabilities, and people with end-stage renal disease. To address this problem, Genetic Alliance recommends creating a mechanism that would assist insurers through the evaluation and subsequent coverage decision-making process, thus improving consumer access to appropriate care across all populations. With the decoding of the human genome and the subsequent move toward personalized medicine, has come a demand for health insurance that recognizes and values individual needs in all populations. As such, technology assessment must be revamped to engage in accurate assessment of new tests and their impact on individuals in addition to larger populations.

We must embrace preventive care as an absolutely essential component of any health care system.

As it stands, coverage for preventive care in public health insurance programs requires Congressional authorization, a fact that significantly limits access to predictive and predispositional genetic tests and services. Furthermore, while private insurers are free to cover these services, too often they follow the lead taken by public programs and exclude the preventive procedures. We at Genetic Alliance recognize the significant value and very often cost-effective nature of preventive care, and we support the Committee's recommendation to "add a benefit category for preventive services." In doing so, the Committee would help establish an environment in which preventive care is appropriately valued.

However, Genetic Alliance also urges the Committee to re-examine the evidence standards used to determine whether or not a procedure—in this case, a preventive procedure—should be covered. As was previously discussed, predictive and predispositional genetic tests and services are often dramatically different from

traditional tests and services. Therefore, these procedures do not necessarily meet the evidence standards outline by the Centers for Medicare & Medicaid Services (CMS). However, genetic tests provide valuable information about an individual's future health risks and can influence health care and lifestyle decisions, much like mammography and newborn screening programs. As such, we should encourage coverage for these services to ensure broad access for all consumers.

Once again, I thank you for the opportunity to address this Committee. Should you desire it, I am happy to provide documentation to support these suggestions. Please, feel free to contact me.

Sharon F. Terry
President and CEO
Genetic Alliance, Inc.
4301 Connecticut Ave., NW
Suite 404
Washington, DC 20008-2369

Telephone: **202.966.5557 ext. 213**
Fax: **202.966.8553**

University of Washington
Seattle, Washington 98195-7660

School of Public Health and Community Medicine

Department of Health Services
Box 357660
FAX: (206) 543-3964

Genetic Services Policy Project
Box 354809
(206) 616-3527
genpol@u.washington.edu

May 5, 2005

Reed V. Tuckson, M.D.
SACGHS Chair
Secretary's Advisory Committee on Genetics, Health, and Society
Department of Health and Human Services
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892-7985

Dear Dr. Tuckson:

Thank you for the opportunity to review and comment on the draft report titled, "Coverage and Reimbursement of Genetic Tests and Services." On behalf of the Genetic Services Policy Project (GSPP), I would like to commend the committee members and staff for addressing this important issue in the delivery of genetic services. I would also like to offer a few comments based on our experience in the GSPP.

As the report cogently points out, genetic services have great potential for improving health for many people. However, in the current fiscal environment, increasing access to genetic services means decreasing access to other beneficial services. When resources are scarce, effectiveness is a necessary but not sufficient condition for coverage. The new service competes for dollars with other health care services that are also effective (although perhaps for other conditions and/or other people). In addition, dollars spent on health care, particularly public health care dollars, compete with dollars spent on other (non-health care) services of value. Thus, as with many new medical technologies, expanding coverage for genetic services should proceed thoughtfully and with consideration for competing demands on resources.

GSPP is a federally-funded collaborative effort between the University of Washington, the Washington State Department of Health, and the Fred Hutchinson Cancer Research Center. The purpose of the project is to describe the current genetic services delivery system; collect, develop, and disseminate information to stakeholders; and to propose alternative genetic services delivery models through consultation with a diverse advisory committee, which comprises representatives from various key stakeholder groups. GSPP is supported by projects # U35MC02601 and # U35MC02602 from the Maternal and Child Health Bureau (Title V, Social Security Act), #11223, Health Resources and Services Administration, Department of Health and Human Services

Emblem: . . . a Northwest Coast Indian symbol of physical and mental well-being.
Artist: Marvin Oliver

Determining the right trade-off among alternative services that have potential health benefit, particularly when the distribution of benefits across different populations is uneven, necessarily involves value judgments. The committee's report and proposed recommendations state very clearly the values and perspectives of genetic services providers. This is certainly an important perspective. However, there are other perspectives that are not reflected in the report. In our experience working with a diverse advisory committee representing providers, business, payers (public and private), consumers, and policy makers, we have found that these groups often have different views. In our opinion, considering many perspectives on the issues central to genetic services financing and delivery is not only useful but also provides the appropriate balancing of science and values.

Overall, the draft report is a well-written, thoughtful description and analysis of coverage and reimbursement issues as related to genetic tests and services. Thank you for giving your attention to this issue.

Sincerely,

Carolyn Watts

Carolyn (Cindy) Watts, Ph.D.
Professor
Genetic Services Policy Project

May 6, 2005

Attn: Suzanne Goodwin
Secretary's Advisory Committee on Genetics
Health, and Society NIH Office of Biotechnology Activities
6705 Rockledge Dr. – Suite 750
Bethesda, MD 20892

To Whom it May Concern,

I write on behalf of the Genetic Task Force of Illinois (GTFI), whose members include medical genetics professionals (physicians, researchers, genetic counselors, and other professionals) from the state of Illinois. Our organization often advocates for the consumers of genetic services in our state, as well facilitating cooperation between professionals and institutions to expand services.

We are proud to say that our state recently passed a new law which requires professionals providing genetic counseling to have had appropriate training (in the form of rigorous certification by the American Board of Genetic Counselors (ABGC), or the American Board of Medical Genetics (ABMG), or related organizations) in order to gain licensure to practice. It is our hope that this law will allow us to monitor and maintain high standards for these services in our state.

We write today regarding the "Draft Report on Coverage and Reimbursement of Genetic Tests and Services" that the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) recently published, specifically, "recommendation 7", genetic counseling services and reimbursement issues. We certainly appreciate that the secretary's committee is attempting to address this issue and all the work which obviously went into creating this document.

We believe access to Genetic Counseling services are limited by the inability – under the current system - to bill 3rd party payers independently. Most genetic providers in our state are based in the Chicago area, in large tertiary centers. Rural areas, as well as other downstate areas have almost no providers with training in this area. In addition, billing for these services under a supervising physician's name is generally poorly reimbursed. **For these reasons, we respectfully request that the Committee *specifically* include ABGC-certified Genetic Counselors as qualified providers who should have the ability to bill independently, in addition to other "non-physician providers".**

We certainly understand that your committee does not decide who can bill independently, however we hope that your document will provide information and guidance to legislators and the policies of 3rd party payer organizations.

We appreciate your hard work and your willingness to receive feedback from professionals and consumers to inform your report. If you have any further questions for our organization, please feel free to contact us.

Sincerely,
Kelly Moyer, MS, CGC
President
Genetic Task Force of Illinois
(708) 216-8167
kmoyer@lumc.edu

GroupHealth
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Partners in health care with Group Health Cooperative

Administrative and Conference Center
521 Wall Street
Seattle, WA 98121
www.ghc.org

May 6, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: Secretary's Advisory Committee on Genetics, Health, and Society
Via Email: goodwins@od.nih.gov

Dear Ms. Goodwin:

I am pleased to submit comments on behalf of Group Health Permanente, an 840-physician multi-specialty medical group located in Washington State. Group Health Permanente (GHP), within its group practice and through contracts with over 6,000 community clinicians and hospitals, provides comprehensive medical services to over 540,000 Group Health members throughout Washington and eastern Idaho.

We would like to commend the work of the Secretary's Advisory Committee on Genetics, Health and Society, for the comprehensive and thoughtful recommendations on genetic screening and counseling services. GHP has a half-time geneticist on staff, employs and contracts with genetic counselors, and provides a full spectrum of genetic screening and counseling services to Group Health members and their families.

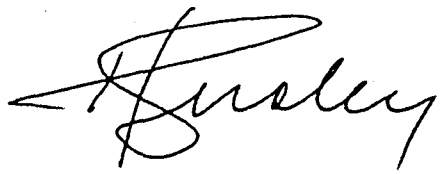
GHP's overall practice philosophy is premised on the provision of comprehensive preventive services, based on solid medical evidence, in partnership with informed and involved patients. GHP believes in providing the right care to patients, at the right time and in the most appropriate setting.

Therefore, we firmly believe that effective and valuable genetic screening and counseling services can and should be provided by credentialed non-physician providers, who act in support of medical geneticists. We further agree with the SACGHS recommendation regarding better coding and reimbursement for genetic screening and counseling services provided by genetic counselors. Such coding and reimbursement enhancements will result in better

workload tracking and care management for at-risk patients, with the likelihood of greater access to medically indicated genetic screening and counseling services over time.

Thank you for the opportunity to comment.

Sincerely,



Hugh Straley, M.D.
President, Group Health Permanente
Medical Director, Group Health Cooperative

PARTNERS

HARVARD
MEDICAL SCHOOL

Scientific Director
Harvard-Partners Center for Genetics and Genomics
77 Louis Pasteur Avenue, Suite #250
Boston, Massachusetts 02115

Tel: 617 525-4445, Fax: 617 525-4440
E-mail: rkucherlapati@partners.org

Raju Kucherlapati
Paul C. Cabot Professor of Genetics
Professor of Medicine
Harvard Medical School

April 25, 2005

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin:

As Scientific Director for Harvard-Partners Center for Genetics and Genomics (HPCGG), I am writing to comment on the draft recommendations regarding coverage and reimbursement that the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) has recently published. HPCGG was founded in 2001 with the mission to promote genetics and genomics in research and clinical medicine, and I am the founding scientific director for this program. We have an active research and clinical program in Human Genetics. We also have established a CLIA laboratory that provides genetic testing for a diverse group of individuals around the world. As you can understand, coverage and reimbursement for genetics services and genetic testing is very important to our center.

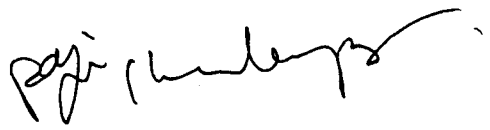
I would specifically like to comment on "Recommendation #7", regarding genetic counseling services and reimbursement issues. As you know, access to genetic counseling services is of the utmost importance. Currently, genetic counselors are not providers that are recognized by CMS, which makes their services non-billable. This is a major obstacle and prevents many individuals from seeking and obtaining genetic counseling services, which in many cases are necessary for both individual and public health reasons. *Thus, I specifically request that the recommendations to the Secretary include ABGC certified genetic counselors as qualified providers who should have the ability to bill independently.*

I would like to commend the SACGHS on their efforts and an excellent document. The remainder of the recommendations regarding genetic counseling service coverage and reimbursement, including the reimbursement of prolonged

service codes both for direct and incident to billing are inclusive and important. I also support the inclusion of non-physician health care providers eligible to directly bill health plans as eligible for national provider identifier (which will replace UPINs).

Thank you for the opportunity to comment on these recommendations, and I look forward to reading them in their final form.

Sincerely,



IHF INSTITUTE for HEALTH
F·R·E·E·D·O·M

May 5, 2005

Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)
Attn: Suzanne Goodwin
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Re: Public Comments

Dear SACGHS Advisory Committee:

Thank you for the opportunity to submit public comments that will be included in the SACGHS's final report titled "Coverage and Reimbursement of Genetic Tests and Services."

From a patient's rights perspective, two of the most important issues to consider with genetic testing are ***informed consent*** and ***privacy***. According to a September 2000 Gallup survey titled "Public Attitudes Toward Medical Privacy," 86 percent of adults believe a physician should ask permission before running additional tests (during the course of regular testing) for genetic factors that may be related to possible health problems. The national survey also found that 93 percent said medical and government researchers should ***not*** be allowed to study an individual's genetic information ***unless they first obtain his or her consent***. Clearly, consent of the governed (or treated) is a founding principle that is still cherished by most Americans today.

On behalf of the Institute for Health Freedom (IHF), I respectfully request that you include these significant national survey findings in the SACGHS's final report. Enclosed is a copy of the Gallup survey for your information.

What's more, Twila Brase, president of the Minnesota-based patients' rights group Citizens' Council on Health Care, points out that some of the implications of unconsented genetic research include the following:

- potential discrimination in insurance coverage and employment;
- lawsuits against health-care institutions;
- violation of religious or cultural beliefs;
- psychological and financial impacts of predictive testing;
- distrust of medical institutions; and
- statutory restrictions on lifestyle, marriage, or procreative choices.

Common sense says that if insurers start covering/increase coverage for genetic testing, they will have increased access to genetic information and therefore a greater opportunity to discriminate

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for genetic-related purposes. It is imperative that the American public and federal committees become informed about how the federal medical privacy rule (released in December 2000 and modified in August 2002) eliminated the precious right to give or withhold consent before one's personal health information—including genetic information—can be accessed by many others, including insurers. **Until the right of consent is restored, recommending the collection, testing and sharing of genetic information is a recipe for increased privacy invasions and discrimination.**

What the Public Wants

It is clear from thousands of public comments submitted to the U.S. Department of Health and Human Services (HHS) and public opinion polls that Americans highly value and expect medical privacy. Citizens want to exercise their right to give or withhold consent before their personal health information is shared with others. Unless the right to consent is upheld, there is no way to ensure that citizens will have control over the flow of their personal health information and thus be able to exercise their right to privacy regarding health matters.

What the Public Does *Not* Want

Citizens do ***not*** want third parties to access their personal health information without first getting citizens' consent:

- "59 percent of Americans reported that they worry that an unauthorized person will gain access to their information. A recent survey suggests that 75 percent of consumers seeking health information on the Internet are concerned or very concerned about the health sites they visit sharing their personal health information with a third party without their permission."[1]
- 78 percent feel it is very important that their medical records be kept confidential.[2]
- 67 percent oppose researchers seeing their medical records without the patient's permission.[3]
- 82 percent object to ***insurance companies*** gaining access without permission.[4]
- 92 percent oppose allowing government agencies to see their medical records without their permission.[5]
- 91 percent oppose a federal requirement to assign everyone a medical identification number, similar to a Social Security number, to create a national medical database.[6]

Since the federal medical privacy rule eliminated the right to give or withhold consent before one's personal health information can be accessed by many others, it is clear that combining the lack of consent with adopting electronic medical records could lead to a greater number of persons accessing patients' medical records—including genetic information—without their permission.

L (lack of consent) + E (electronic records/easier access) = Increased Privacy Invasions

HHS acknowledges this fact, stating: "The electronic information revolution is transforming the recording of health information so that the disclosure of information may require only a push of a button. ***In a matter of seconds, a person's most profoundly private information can be shared with hundreds, thousands, even millions of individuals and organizations at a time.***"[7] [Emphasis added]

Why Medical Privacy Matters

HHS has identified some of the major reasons why medical privacy is important:

Privacy is essential to receiving quality health care.

- "In short, the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers. The need for privacy of health information, in particular, has long been recognized as critical to the delivery of needed medical care. More than anything else, the relationship between a patient and a clinician is based on trust. The clinician must trust the patient to give full and truthful information about their health, symptoms, and medical history. The patient must trust the clinician to use that information to improve his or her health and to respect the need to keep such information private. In order to receive accurate and reliable diagnosis and treatment, patients must provide health care professionals with accurate, detailed information about their personal health, behavior, and other aspects of their lives. The provision of health information assists in the diagnosis of an illness or condition, in the development of a treatment plan, and in the evaluation of the effectiveness of that treatment. In the absence of full and accurate information, there is a serious risk that the treatment plan will be inappropriate to the patient's situation....***Individuals cannot be expected to share the most intimate details of their lives unless they have confidence that such information will not be used or shared inappropriately***. Privacy violations reduce consumers' trust in the health care system and institutions that serve them. Such a loss of faith can impede the quality of the health care they receive, and can harm the financial health of health care institutions."[8] [Emphasis added]

- "Patients who are worried about the possible misuse of their information often take steps to protect their privacy. Recent studies show that a person who does not believe his privacy will be protected is much less likely to participate fully in the diagnosis and treatment of his medical condition.... ***[O]ne in six Americans reported that they have taken some sort of evasive action to avoid the inappropriate use of their information by providing inaccurate information to a health care provider, changing physicians, or avoiding care altogether.***"[9] [Emphasis added]

Other harms from privacy breaches identified by HHS:

"A breach of a person's health privacy can have significant implications well beyond the physical health of that person, including the loss of a job, alienation of family and friends, the loss of health insurance, and public humiliation. For example:"[10]

- "A banker who also sat on a county health board gained access to patients' records and identified several people with cancer and called in their mortgages. See the *National Law Journal*, May 30, 1994."[11]

- "A physician was diagnosed with AIDS at the hospital in which he practiced medicine. His surgical privileges were suspended. See *Estate of Behringer v. Medical Center at Princeton*, 249 N.J. Super. 597."[12]

- "A candidate for Congress nearly saw her campaign derailed when newspapers published the fact that she had sought psychiatric treatment after a suicide attempt. See *New York Times*, October 10, 1992, Section 1, page 25."[13]

- "A 30-year FBI veteran was put on administrative leave when, without his permission, his pharmacy released information about his treatment for depression. (*Los Angeles Times*, September 1, 1998)"[14]

Increasing the use of interconnected electronic information systems brings new potential for invasions of our privacy.

- "A series of national public opinion polls conducted by Louis Harris & Associates documents a rising level of public concern about privacy, growing from 64 percent in 1978 to 82 percent in 1995. Over 80 percent of persons surveyed in 1999 agreed with the statement that they had 'lost all control over their personal information.'... This growing concern stems from several trends, including the growing use of ***interconnected electronic media*** for business and personal activities, our increasing ability to know an individual's genetic make-up, and, in health care, the increasing complexity of the system. Each of these trends brings the potential for tremendous benefits to individuals and society generally. At the same time, ***each also brings new potential for invasions of our privacy***."[15] [Emphasis added]

- "Until recently, health information was recorded and maintained on paper and stored in the offices of community-based physicians, nurses, hospitals, and other health care professionals and institutions....Today, however, more and more health care providers, plans, and others are utilizing electronic means of storing and transmitting health information. In 1996, the health care industry invested an estimated $10 billion to $15 billion on information technology....The electronic information revolution is transforming the recording of health information so that the disclosure of information may require only a push of a button. ***In a matter of seconds, a person's most profoundly private information can be shared with hundreds, thousands, even millions of individuals and organizations at a time***. While the majority of medical records still are in paper form, information from those records is often copied and transmitted through electronic means."[16] [Emphasis added]

- "This ease of information collection, organization, retention, and exchange made possible by the advances in computer and other electronic technology affords many benefits to individuals and to the health care industry....At the same time, these advances have reduced or eliminated many of the financial and logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals. And they have made our information available to many more people....***In an earlier period where it was far more expensive to access and use medical records, the risk of harm to individuals was relatively low. In the potential near future, when technology makes it almost free to send lifetime medical records over the Internet, the risks may grow rapidly***. It may become cost-effective, for instance, for companies to offer services that allow purchasers to obtain details of a person's physical and mental treatments. In addition to legitimate possible uses for such services, malicious or inquisitive persons may download medical records for purposes ranging from identity theft to embarrassment to prurient interest in the life of a celebrity or neighbor....***[M]any persons believe that they have a right to live in society***

without having these details of their lives laid open to unknown and possibly hostile eyes. These technological changes, in short, may provide a reason for institutionalizing privacy protections in situations where the risk of harm did not previously justify writing such protections into law."[17] [Emphasis added]

As HHS acknowledges, "Unless public fears [about medical privacy invasions] are allayed, we will be unable to obtain the full benefits of electronic technologies."[18]

Summary

Without addressing the ***informed consent*** and ***medical privacy*** issues cited in these comments, moving forward with recommending increased genetic testing and data collection would be a violation of the founding principle of "consent of the governed": the right to determine and control who has access to one's personal health information, ***especially genetic information***.

Thank you again for the opportunity to have these important patients' rights perspectives and concerns about informed consent and medical privacy included in the SACGHS's final report.

Sincerely,

Sue A. Blevins

Sue A. Blevins
President

Enclosure: Copy of Gallup survey titled "Public Attitudes Toward Medical Privacy"

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[1] *Federal Register*, (Volume 65, Number 250), December 28, 2000, page 82466.
[2] "Public Attitudes Toward Medical Privacy," Gallup Survey, September 2000.
[3] Ibid.
[4] Ibid.
[5] Ibid.
[6] Ibid.
[7] *Federal Register*, (Volume 65, Number 250), December 28, 2000, page 82465.
[8] Ibid, pp. 82467-8.
[9] Ibid, p. 82468.
[10] Ibid, p. 82468.
[11] Ibid, p. 82468.
[12] Ibid, p. 82468.
[13] Ibid, p. 82468.
[14] Ibid, p. 82468.
[15] Ibid, p. 82465.
[16] Ibid, p. 82465.
[17] Ibid, pp. 82465-6.
[18] Ibid, p. 82466.

Public Attitudes Toward Medical Privacy

Submitted to:

The Institute for Health Freedom

September, 2000

Submitted by:

THE GALLUP ORGANIZATION

47 Hulfish Street
Princeton, New Jersey 08542

Contents

Introduction

This report is based on the results of a survey conducted by The Gallup Organization on behalf of the Institute for Health Freedom. The opinions of a national cross-section of adults in telephone owning households, 18 years of age or older, concerning access and the confidentiality of their medical records were obtained.

A national cross-section of telephone households was systematically selected using random digit dialing techniques to ensure the inclusion of households with both listed and unlisted telephone numbers. Everyone was interviewed between August 11, 2000 to August 26, 2000. A total of 1,000 interviews were completed. Results based on the entire sample are accurate with a plus or minus 3-percentage point margin of error at the 95% confidence level. The sampling tolerances will be found in the technical appendix of this report.

Overview of Survey Findings

For most adults the confidentiality of their medical records is very important, and only the confidentiality of financial information is judged very important by a greater proportion. Over eight in ten adults (84%) report it is very important that their financial information be kept confidential. Almost as many (78%) feel it is very important that their medical records be kept confidential. While important to many adults, less than half (39%) feel it is very important that their employment history be kept confidential, and fewer (30%) feel it is very important that their educational history be kept confidential.

Women are more likely than men to feel it is very important their medical records should be kept confidential (81% and 74%, respectively). In addition, older adults, particularly those 35 to 49, are more likely than adults 18 to 34 years of age to say it is very important that their medical records be kept confidential.

Given the importance attached to keeping their medical records confidential, it is not surprising that many adults oppose access by any group. Asked if they favored or opposed allowing various groups to see their medical records without permission there is no group that a majority of adults would favor allowing access to their medical records without their authorization.

The most "acceptable" group would be pharmacists, four in ten adults (40%) would favor allowing pharmacists to see their medical records without permission while 59% would be opposed.

There is strong opposition to non-medical groups gaining access to their medical records. Nine out of ten (92%) oppose giving government agencies access. About as many (88%) oppose the police or lawyers, or employers (84%) being allowed to see their medical records. Similarly, 82% oppose letting insurance companies see their medical records without permission. Over nine in ten (95%) oppose allowing banks to see their medical records without permission.

Local and state health departments are acceptable to a larger proportion compared to government agencies overall, nevertheless, 71% oppose giving these agencies access to medical information without permission.

Opinion is no different when it comes to medical doctors other than those given permission by the respondent. Seven in ten (71%) oppose giving doctors access to their medical records without permission. Medical researchers would be denied access too – two-thirds (67%) oppose allowing researchers permission to see their medical records without permission.

While controlling access to their medical records is important to many, relatively few adults (16%) have heard or read anything recently about new federal regulations that would change the rules regarding access to medical records. Adults, age 50 or older (20%) and college-educated adults (19%) are more likely than others to say they have heard about the issue.

Asked their opinion of keeping their medical records in a national computerized database, most adults (88%) are opposed. Only 10% would favor keeping records in a national database. Adults, ages 35 to 49 are more likely than younger or older adults to oppose a national database for medical records. Similarly, college-educated adults are more likely than those with fewer years of formal education to oppose a national database (93% and 83%, respectively).

Few adults (12%) have seen or heard anything recently about a proposal to assign medical identification numbers. Even fewer (8%) adults support a plan that requires every American to be assigned a medical identification number. Adults 35 years of age or older are more likely than younger adults to be aware of the medical identification proposals.

Over nine in ten adults (95%) say doctors and hospitals should have to obtain their permission before releasing medical records to a national database. In addition, only 4% believe personal information told a doctor in confidence and entered into their medical records should be included in the national database.

Most adults (86%) feel a physician should ask permission first before running additional tests, during the course of regular testing, for genetic factors that may be related to possible health

problems. Approximately one in seven (14%) feel the physician should be allowed to run the additional tests without asking permission.

Over nine in ten adults (93%) feel medical and government researchers should obtain permission before studying a person's genetic information. Less than one in ten (6%) feel it isn't necessary to obtain the person's permission.

Detailed Findings

Importance of Confidentiality of Information

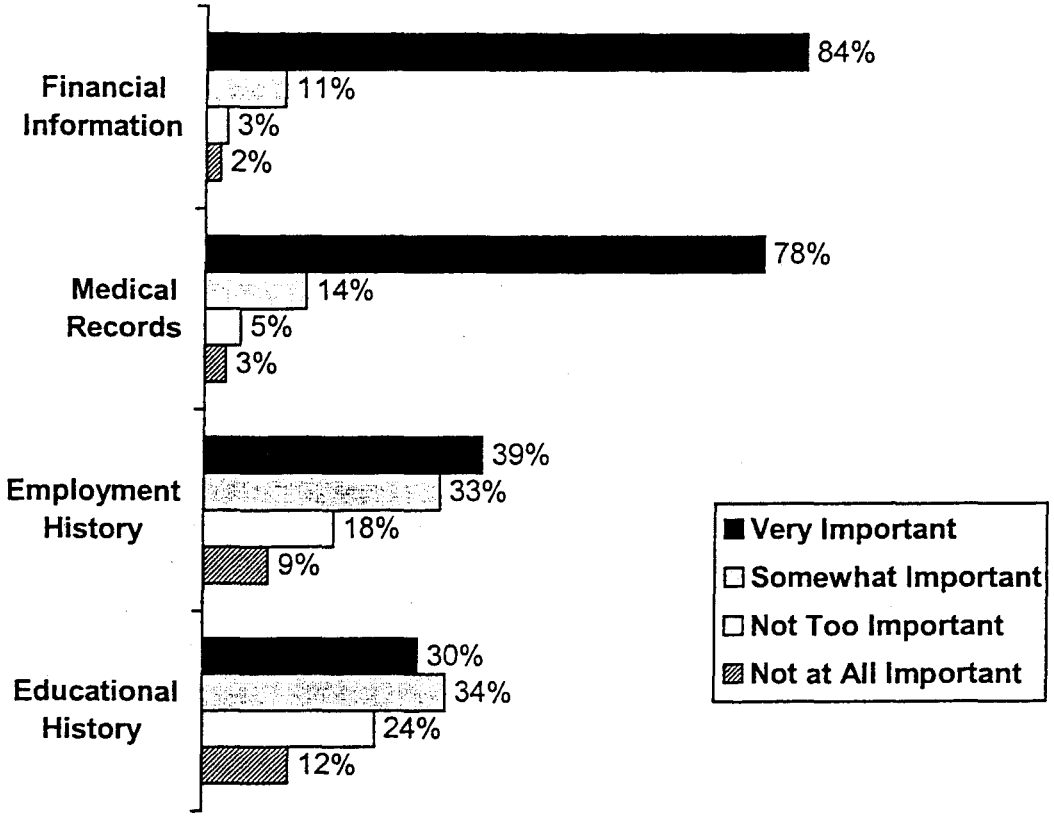
Question 1

How important is it to you that information in the following areas be kept confidential; that is, no one can see it without your permission - very important, somewhat important, not too important, or not at all important?

-Financial information
-Employment history
-Medical records
-Educational history

Over eight in ten adults (84%) report it is very important that their financial information be kept confidential. Almost as many (78%) feel it is very important that their medical records be kept confidential. While important to most adults, less than half (39%) feel it is very important that their employment history be kept confidential, and fewer (30%) feel it is very important that their educational history be kept confidential.

IMPORTANCE OF CONFIDENTIALITY (n=1000)



- Women are more likely than men to feel it is very important their medical records should be kept confidential (81% and 74%, respectively).
- Older adults, particularly those 35 to 49 (83%), are more likely than adults 18 to 34 years of age (71%) to say their medical records should be kept confidential.
- Women and adults, 35 to 49 years of age, are more likely than others to consider keeping their financial information confidential very important.

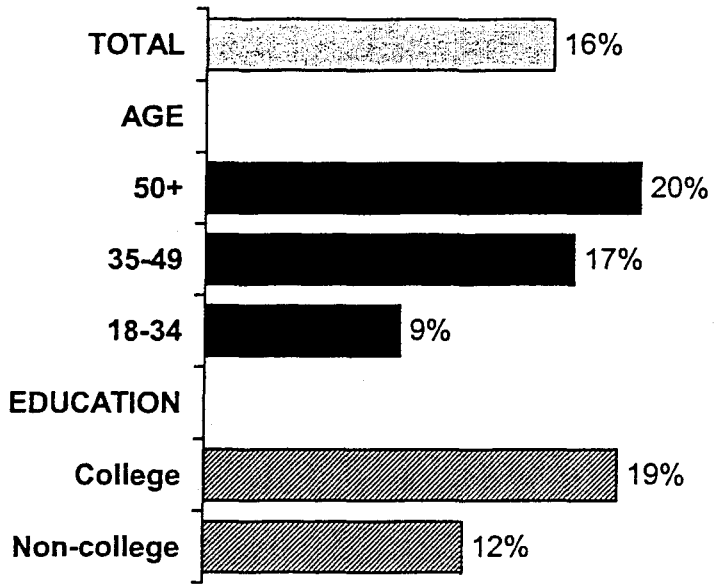
Awareness of Federal Regulations Regarding Access to Medical Records

Question 2

Have you heard, read or seen anything recently about new federal regulations that would change the rules regarding who is allowed to see your medical records?

Relatively few adults (16%) have heard or read anything recently about new federal regulations that would change the rules regarding access to medical records. Adults, age 50 or older (20%) and college-educated adults (19%) are more likely than others to say they have heard about the issue.

AWARE OF NEW FEDERAL REGULATIONS REGARDING MEDICAL RECORDS (n=1000)



Favor or Oppose Access to Medical Records by Selected Groups

Question 3

Who do you think should be allowed to see your medical records without your permission? I am going to read you a list of some groups; for each, please tell me whether you favor or oppose allowing them to see YOUR medical records without FIRST obtaining YOUR permission. How about . . .?

- Medical doctors OTHER than the ones you have given permission
-Pharmacists
-Medical researchers
-The police or lawyers
-Local and state health departments
-Banks
-Insurance companies
-Employers
-Government agencies

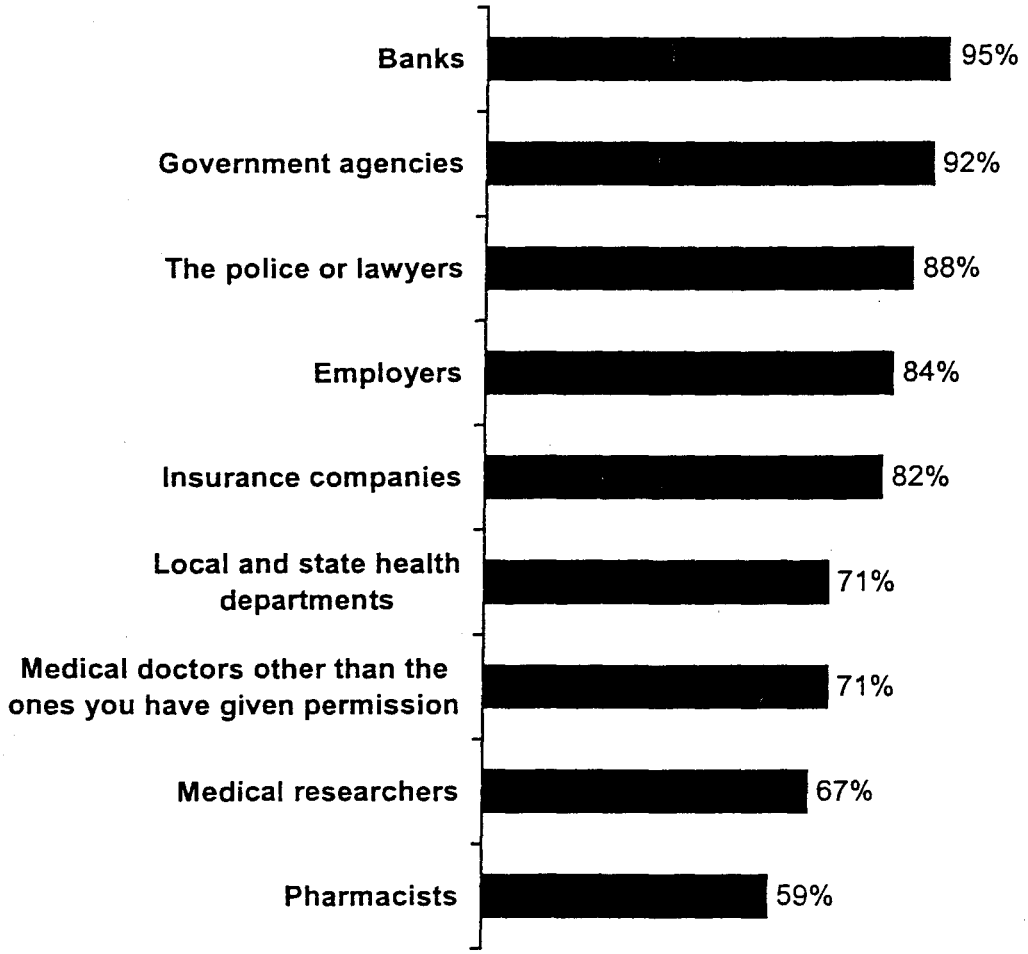
Asked if they favored or opposed allowing various groups to see their medical records without permission there is no group that a majority of adults would favor allowing access to their medical records without their authorization.

The most "acceptable" group would be pharmacists. Four in ten adults would favor allowing pharmacists to see their medical records without permission while 59% would be opposed. In contrast, the least "acceptable" group would be banks, only 5% would favor allowing banks to see their medical records without permission.

There is strong opposition to other non-medical groups seeing their medical records. Nine out of ten (92%) oppose giving government agencies access. About as many (88%) oppose the police or lawyers, or employers (84%) being allowed to see their medical records. Similarly, 82% oppose letting insurance companies see their medical records without permission.

Local and state health departments are acceptable to a larger proportion compared to government agencies overall, however, 71% oppose giving these agencies access to medical information without permission, too. Opinion is no different when it comes to medical doctors other than ones given permission by the respondent. Seven in ten (71%) oppose giving doctors access to their medical records without permission. Medical researchers fare no better than doctors – two-thirds (67%) oppose allowing researchers permission to see their medical records without permission.

PROPORTION OPPOSED TO ALLOWING GROUP TO SEE MEDICAL RECORDS (n=1000)



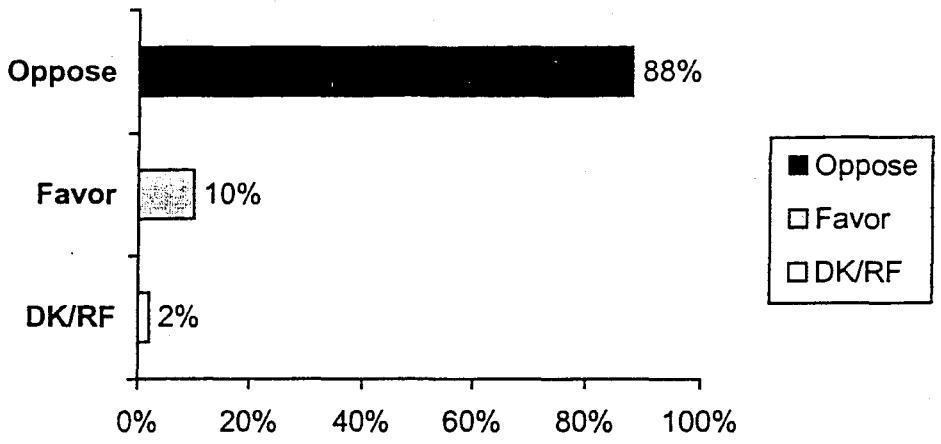
Attitude Toward National Database

Question 4

There has been a lot of discussion lately about REQUIRING that all patient medical records be stored in a national computerized database. The database would store medical records on patients over their lifetime. Others would be able to use the information without first obtaining a patient's permission. Would you favor or oppose keeping your medical records this way?

Most adults (88%) are opposed to keeping their medical records in a national computerized database. Only 10% would favor the plan described to them.

FAVOR/OPPOSE STORING MEDICAL RECORDS IN COMPUTERIZED DATABASE (n=1000)



- Adults, ages 35 to 49 are more likely than younger or older adults to oppose a national database for medical records (92%).
- College-educated adults are more likely than those with fewer years of formal education to oppose a national database (93% and 83%, respectively).

Awareness and Support for Medical Identification Numbers

Question 5

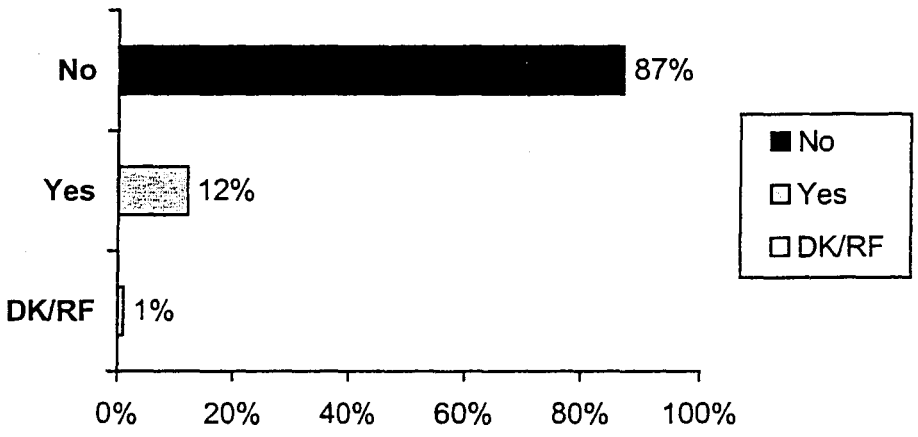
Have you heard, read or seen anything recently about a federal proposal to assign medical identification numbers, similar to a social security number, to you and all other Americans to create a national database of medical records?

Question 6

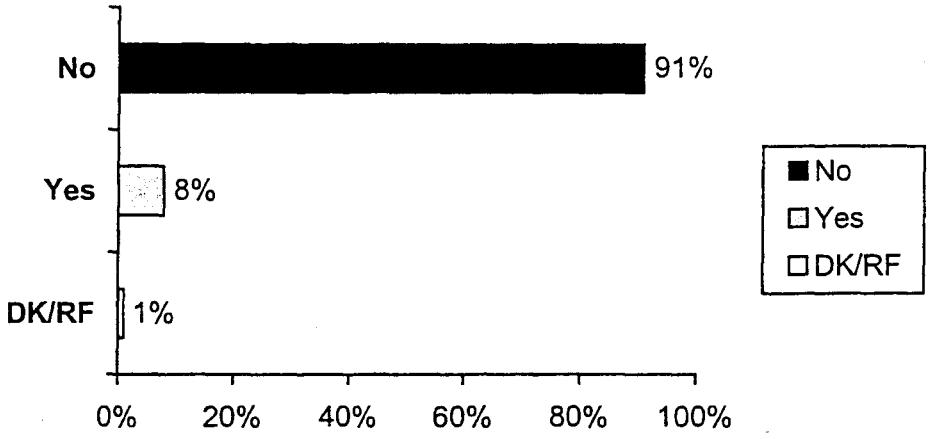
Would you support a plan that REQUIRES every American, including you, to be assigned a medical identification number, similar to a social security number, to track your medical records and place them in a national computer database without your permission?

One in eight adults (12%) have seen or heard something recently about a proposal to assign medical identification numbers. Somewhat fewer (8%) adults support a plan that requires every American to be assigned a medical identification number.

AWARE OF FEDERAL PROPOSAL REGARDING MEDICAL ID NUMBERS (n=1000)



SUPPORT PLAN THAT REQUIRES ASSIGNED MEDICAL ID NUMBER (n=1000)



- Adults 35 years of age or older are more likely than younger adults to be aware of the medical identification proposals (14% and 7%, respectively).
- College-educated adults (16%) are more likely than those with less than a college education (8%) to say they are aware of proposals for medical identification numbers.
- Support for medical identification numbers is highest in the Midwest (12%) and lowest in the West (3%).

Should Permission Be Obtained Before Releasing Information to National Database?

Question 7

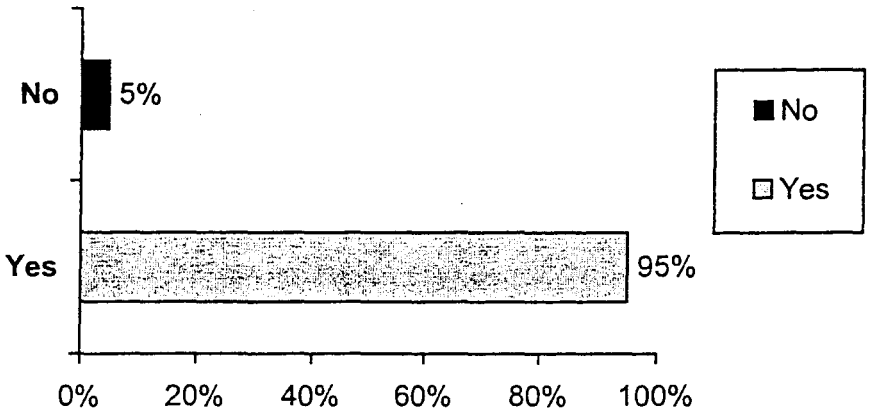
Do you think doctors and hospitals should have to obtain your PERMISSION before they could release your medical records to a national computerized database?

Question 8

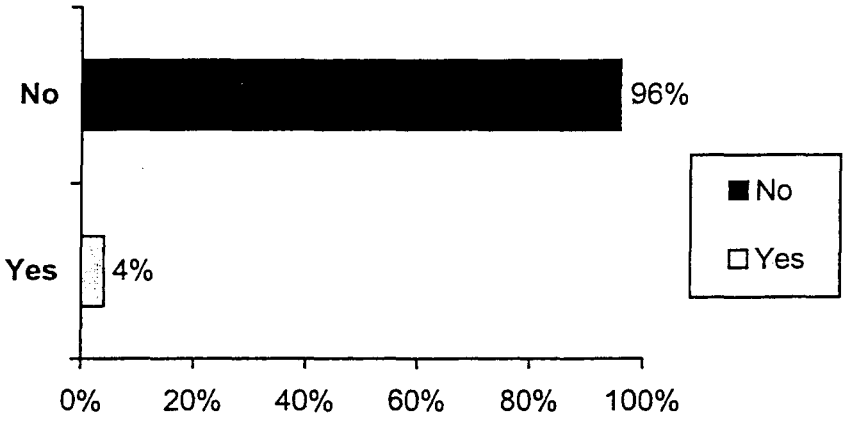
If you tell a doctor personal things about yourself in confidence, and the doctor records that information in your medical records, should the doctor be required to include that information in a national database without your permission?

Over nine in ten adults (95%) say doctors and hospitals should have to obtain their permission before releasing medical records to a national database. In addition, only 4% believe personal information told a doctor in confidence and entered into their medical records should be included in the national database.

PERMISSION SHOULD BE OBTAINED BEFORE RELEASING MEDICAL RECORDS (n=1000)



SHOULD PERSONAL INFORMATION TOLD TO MEDICAL DOCTOR IN CONFIDENCE BE INCLUDED IN NATIONAL DATABASE? (n=1000)



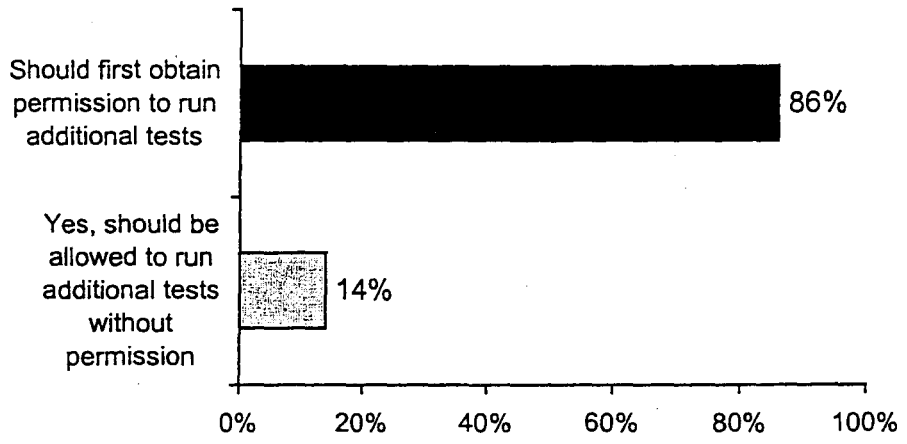
Should Physicians Be Allowed to Test for Genetic Factors Without Permission?

Question 9

If you go to a DOCTOR to have your blood tested for sugar or for high cholesterol, should your doctor also be allowed to test your blood for genetic factors that, for example, could reveal whether you are prone to cancer later in life, without first obtaining your permission, or do you feel your doctor should first obtain your permission?

Most adults (86%) feel a physician should ask permission first before running additional tests, during the course of regular testing, for genetic factors that may be related to possible health problems. Approximately one in seven (14%) feel the physician should be allowed to run the additional tests without asking permission.

SHOULD DOCTOR TEST FOR GENETIC FACTORS WITHOUT PERMISSION? (n=1000)



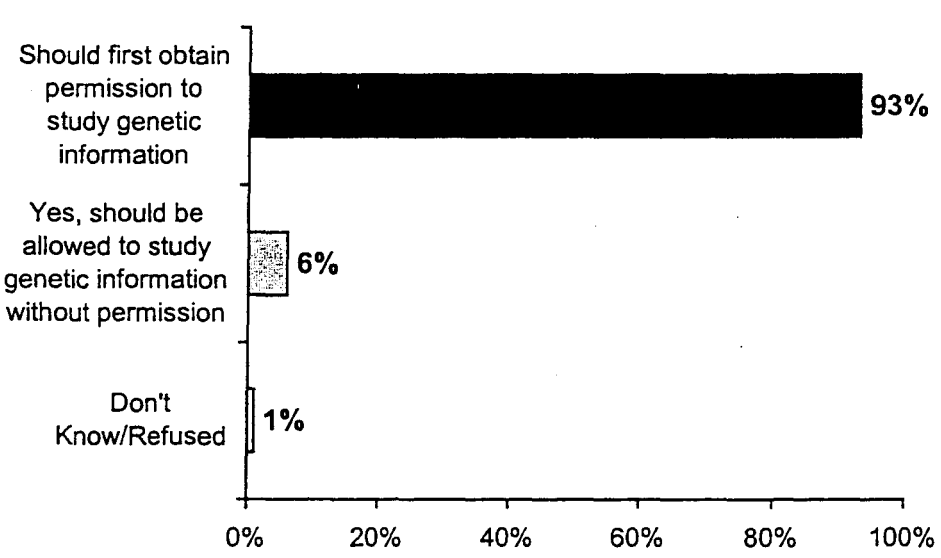
- Women (88%) are more likely than men (84%) to feel a physician should ask permission before conducting additional tests.

Should Researchers Be Allowed to Study Genetic Information Without Permission?

Question 10

Should medical and government RESEARCHERS be allowed to STUDY your genetic information (for example, to identify genes thought to be associated with various medical conditions) without first obtaining your permission, or do you feel they should first obtain your permission?

Over nine in ten adults (93%) feel medical and government researchers should obtain permission before studying a person's genetic information. Less than one in ten (6%) feel it isn't necessary to obtain the person's permission.



Appendix A

Sampling Tolerances

Sampling Tolerances

In interpreting survey results, it should be borne in mind that all sample surveys are subject to sampling error, that is, the extent to which the results may differ from what would be obtained if the whole population had been interviewed. The size of such sampling errors depends largely on the number of interviews.

The following tables may be used in estimating the sampling error of any percentage in this report. The computed allowances have taken into account the effect of the sample design upon sampling error. They may be interpreted as indicating the range (plus or minus the figure shown) within which the results of repeated samplings in the same time period could be expected to vary, 95 percent of the time, assuming the same sampling procedures, the same interviewers, and the same questionnaire.

The first table shows how much allowance should be made for the sampling error of a percentage:

Recommended Allowance for Sampling Error of a Percentage

In Percentage Points (at 95 in 100 confidence level)*

		Sample Size					
		1000	800	600	400	300	200
PERCENTAGES NEAR	10	2	2	3	3	4	5
PERCENTAGES NEAR	20	3	3	4	4	5	6
PERCENTAGES NEAR	30	3	3	4	5	6	7
PERCENTAGES NEAR	40	3	4	4	5	6	7
PERCENTAGES NEAR	50	3	4	4	5	6	8
PERCENTAGES NEAR	60	3	4	4	5	6	7
PERCENTAGES NEAR	70	3	3	4	5	6	7
PERCENTAGES NEAR	80	3	3	4	4	5	6
PERCENTAGES NEAR	90	2	2	3	3	4	5

* THE CHANCES ARE 95 IN 100 THAT THE SAMPLING ERROR IS NOT LARGER THAN THE FIGURE SHOWN.

The table would be used in the following manner: Let us say a reported percentage is 33 for a group which includes 1000 respondents. Then we go to row "percentages near 30" in the table and go across to the column headed "1000". The number at this point is 3, which means that the 33 percent obtained in the sample is subject to a sampling error of plus or minus 3 points.

Another way of saying it is that very probably (95 chances of 100) the true figure would be somewhere between 30 and 36, with the most likely figure the 33 obtained.

In comparing survey results in two samples, such as, for example, men and women, the question arises as to how large a difference between them must be before one can be reasonably sure that it reflects a real difference. In the tables below, the number of points which must be allowed for in such comparisons is indicated.

Two tables are provided. One is for percentages near 20 or 80; the other for percentages near 50. For percentages in between, the error to be allowed for is between those shown in the two tables.

Recommended Allowance for Sampling
Error of the Difference
In Percentage Points
(at 95 in 100 confidence level)*

TABLE A — Percentages near 20 or percentages near 80

	1000	800	600	400	300	200
1000	4					
800	4	4				
600	4	5	5			
400	5	5	6	6		
300	6	6	6	7	7	
200	7	7	7	7	8	9

TABLE B — Percentages near 50

	1000	800	600	400	300	200
1000	5					
800	5	5				
600	6	6	6			
400	6	7	7	8		
300	7	7	8	8	9	
200	8	9	9	9	10	11

* THE CHANCES ARE 95 IN 100 THAT THE SAMPLING ERROR IS NOT LARGER THAN THE FIGURE SHOWN.

Public Comment to: The Secretary's Advisory Committee on Genetics, Health and Society
From: The International Society of Nurses in Genetics, Inc.
Re: Coverage and Reimbursement of Genetic Tests and Services
Date: May 2, 2005

The International Society of Nurses in Genetics, Inc. (ISONG), an international nursing specialty organization dedicated to fostering the scientific and professional growth of nurses in human genetics, is pleased to submit comments to the Secretary's Advisory Committee on Genetics, Health and Society regarding the document *Coverage and Reimbursement of Genetic Tests and Services.*

ISONG strongly supports the document, especially the following recommendations:

- That genetic tests and services especially those with a prevention component should be considered specifically with respect to the benefits they can offer the populations they serve.
- The need to provide evidence of what broadly could be said to be the 'usefulness' of a test before it is introduced clinically.
- That nurses who are credentialed with the Advanced Practice Nurse in Genetics credential be considered genetics specialists who can bill for the services they provide.
- The importance of ongoing professional and consumer education in genetics.
- That "personal history" includes family history of a particular disease for the purposes of establishing a genetic test is "reasonable and necessary."
- That HHS conduct an assessment of the adequacy of existing CPT E & M codes to better reimburse genetic services.
- That non-physician health professionals (specifically genetics advanced practice nurses and genetic counselors) who are qualified to provide genetic counseling services be able to directly bill for their services.

ISONG also makes the following recommendations that will strengthen and clarify the document:

- ISONG strongly supports the Genetics Nurse Credentialing Commission process for advanced practice nurses in genetics, and SACGHS recognition of this process and credential in the document. However, ISONG believes that SACGHS should also refer to the American Nurses Association Scope and Standards of Practice that allows any advanced practice nurse to order and interpret

diagnostic testing. As genetics becomes more a component of generalist practice, primary care providers including advanced practice nurses will increasingly use genetic testing in their practice (e.g. prenatal multiple marker screening; cystic fibrosis carrier screening), and billing for services. SACGHS should consider including information about levels of genetics services provision with genetics specialists (geneticists, genetic counselors, advanced practice nurses in genetics) providing the most complex genetics services.

- Include a recommendation stating that if a genetic test is positive for a certain condition, insurance coverage for the medically recommended follow-up should also be provided.
- Recommend that Medicare not be used as any kind of benchmark for coverage since most genetic tests are done earlier in life than 65 years old for the purposes of prevention, diagnosis, intervention and management.
- Support nationally established levels of Medicaid coverage.
- Expand the membership on the Pathology Code List to include genetics nurses and genetic counselors, to bring those voices to the table.
- SACGHS should strongly recommend the publication of private insurance companies' payment rates and reimbursement rates as this transparency may lead to more even billing and a willingness for insurance companies to expend coverage.
- Reword the education recommendations to broaden "providers" to "providers and patient care personnel, such as nurses, social workers, psychologists, etc."
- Although the report does not intend to address issues relating to inequity of provision of genetics services, ISONG recognizes that all individuals should be able to access appropriate genetic health care.

Approved by the ISONG Board, April 29, 2005

national society
of genetic
counselors, inc.

nsgc

April 27, 2005

Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Dear Ms. Goodwin:

I am writing on behalf of the National Society of Genetic Counselors (NSGC) to comment on the "Draft Report on Coverage and Reimbursement of Genetic Tests and Services" that the Secretary's Advisory Committee on Genetics, Health and Society (SACGHS) has recently published.

First, NSGC would like to publicly applaud the hard work and thoughtfulness put in by the SACGHS committee to develop a comprehensive set of guidelines in this report. Overall, our organization is very satisfied with the content of the document, which we feel accurately portrays the current status of genetic counselor billing, with the exception of the discussion points included below. We are specifically pleased that the document is accurate, inclusive, and provides concrete recommendations that we feel have the potential to positively impact the billing and coverage of genetic services and testing.

We have the following specific comments regarding the document:

1. Factual corrections and clarifications to the document are as follows:

   - *On page 38 paragraph 2*: The American College of Medical Genetics, in conjunction with the National Society of Genetic Counselors, has resubmitted a proposal for discussion at the June, 2005 meeting of the CPT Editorial panel.

   - *On page 50, first two lines (end of paragraph from prior page)*: While the 2004 NSGC professional status survey (PSS) did document that 9% of respondents reported billing in their own and their supervising physician's names, it seems likely that these individuals were using this mechanism for internal (departmental) tracking of workloads, and that in fact the bills were submitted only in the names of the supervising physicians. The survey did not specifically address this, however. Additionally, the PSS only asked for what respondents reported doing for billing practices, and not their actual practices (no audit was performed). Modifying the language in this section would more accurately reflect the first issue, and we also suggest that revisions clarify that these practices are "reported" rather than actual practices.

- *Regarding footnote #60 (page 51),* we recently became aware that genetic counselor licensure legislation was proposed in Oklahoma earlier this year.

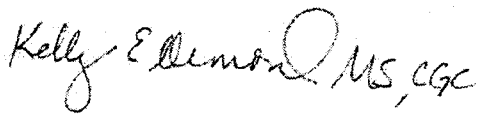
2. With regards to the discussion on page 49 regarding "billing Medicare", as the committee is aware, Master's level trained genetic counselors are NOT considered statutorily eligible to bill Medicare. However, many health care providers and payors are *not aware* of this current ineligibility, and we therefore request that a statement to this effect be added to the paragraph that lists those who are considered eligible.

3. With regards to the potential recommendations listed on page 52, we strongly believe that the workforce materials documented the qualifications and credentials of ABGC certified genetic counselors and GNCC certified genetic nurses.
   - Consistent with the statements on page 48 that there are several "non-physicians providers [who] are uniquely qualified to provide genetic counseling services because of their specialized training and certification," and with the committee's March 1, 2005 discussion, we again request that SACGHS specifically list certified or licensed genetic counselors and certified genetic nurses as those with the credentials described.
   - We ask that the committee separately clarify that other providers may also be considered qualified to provide genetic counseling services in the future, with or without direct billing abilities.
   - Lastly, our organization supports the notion of having additional studies done to consider such other providers.

Finally, NSGC also specifically wants to recognize that while neither SACGHS nor the Secretary of Health and Human Services can directly influence which providers are recognized by Medicare as billable providers, we do feel strongly that any recommendations of the SACGHS committee can be used to help influence Congress and other third party payor organizations which may have the authority to make such decisions regarding qualified providers for genetic services. In our organization's view, the statements of this committee are of utmost importance.

We again thank the SACGHS committee for its diligence in developing a comprehensive document, and for hearing the views of genetic counselors as well as other service providers as you developed this report. If we can be of additional assistance in this or any other matter, please do not hesitate to contact us.

Sincerely,



Kelly E. Ormond, MS, CGC
President
National Society of Genetic Counselors
(312) 926-7466
k-ormond@northwestern.edu

ONCOLOGY NURSING SOCIETY

125 Enterprise Drive • Pittsburgh, PA 15275-1214
Toll Free: 866-257-4ONS • Phone: 412-859-6100 • Fax: 412-859-6165
E-mail: customer.service@ons.org • Web site: www.ons.org

May 6, 2005

Secretary's Advisory Committee on
Genetics, Health, and Society
US Department of Health and Human Services
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892

Dear Committee Members:

On behalf of the Oncology Nursing Society (ONS), a professional organization of more than 33,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing, we are writing to thank you for the opportunity to provide written comments on your draft report, *"Coverage and Reimbursement of Genetic Tests and Services."* We applaud you for your attention to such critical public health concerns and commend you for the excellent work you have done. Generally, we believe that the report is comprehensive and well-written. We do have a number of recommendations and comments, and, as such, respectfully submit this letter and the attached edited version of the report with specific input for your consideration.

ONS has serious concerns that throughout the document there is a lack of consistent use of terminology/nomenclature pertaining to health professionals involved in genetics. For example, while early in the document in some places nurses are included as specific providers of genetics services, wording later is specific only to genetic counselors. Throughout the draft document, ONS notes that genetic counselors as a profession are sometimes equated with genetic counseling as a service, even though the scope of practice of genetic counselors is broader than providing just genetic counseling services and other health providers also provide genetic counseling. As such, the definition of genetic counseling in the report appears to be used to define the scope of practice of genetic counselors, which does not reflect the expansion of genetic counselors into broader roles. ONS appreciates that part of the confusion around the use of these terms may stem from genetic counselors not yet having a published scope and standards of practice.

ONS urges the Committee to include in the report definitions for commonly used language, so as to ensure a uniform understanding of each individual term. Such terms in the report for which ONS recommends definitions and consistent usages be established include: health professionals, providers, genetics professionals, and genetic counselors. Specifically, since genetic counselors may soon be a title protected term in many states, the term "genetics professionals" or "genetics professionals providing genetic counseling" would be more inclusive and descriptive to mean the cadre of individuals providing genetics services. As such, then any time the term "genetic counselor" is used in the report, the reader would be clear that it refers only to genetic counselors and not all the types of health professionals providing genetic counseling. ONS believes that another thorough review of the document to make the terminology consistent throughout, as well as the inclusion of specific definitions for such terms, will strengthen the report.

To assist you in your review of our feedback, the following provides you with an inventory of the sections/page numbers of the attached edited report where we have provided commentary (in red text).

Genetic Tests & Services: Challenges to the U.S. Health Care System - **pp. 15, 16, 18**
Coverage - **pp. 28, 29, 30**
Medicare Coverage - **pp. 31, 33, 34, 35**
Medicaid Coverage - **pp. 37**
Billing and Reimbursement - **pp. 39, 40, 41**
Medicare Clinical Laboratory Fee Schedule - **pp. 48**
Billing and Reimbursement of Genetic Counseling Services - **pp. 52, 53, 54, 55, 56**
Broader Issues - **pp. 57, 58**
Provider Education and Training - **pp. 58**
Public Awareness- **pp. 59**
Report of the Work Group on Genetic Counseling Services - **pp. 77, 79, 80, 81, 82, 87, 90**

ONS again thanks the Committee for the opportunity to provide these comments and stands ready to work with the Committee, the Department of Health and Human Services, the Administration, Congress, and other stakeholders to reduce and prevent suffering from cancer and ensure that all people and their family members have access to the quality genetic testing, counseling, and related care and services they need and deserve.

As always, if we can be of any assistance to you, or if you have any questions, please feel free to contact us or our Washington, DC Health Policy Associate, Ilisa Halpern (202/230-5145, ihalpern@gcd.com).

Sincerely,

Karen J. Stanley

Karen Stanley, RN, MSN, AOCN®, FAAN
President

Pearl Moore

Pearl Moore, RN, MN, FAAN
Chief Executive Officer

Genetic Tests & Services: Challenges to the U.S. Health Care System

Genetic tests are like other laboratory services in that they detect biological products and analytes and can provide diagnostic and predictive information that informs clinical treatment. In other ways, these new technologies and services have expanded and challenged our previous understanding of the role of laboratory services in health care. Genetic tests and services are different (but not necessarily exceptional) in that they are relevant to all clinical disciplines and because they offer more information than traditional laboratory services. In addition to providing diagnostic information, genetic tests have the potential to provide more precise, accurate information about an individual's susceptibility to disease and response to pharmaceuticals. Furthermore, because genes are inherited, genetic tests can clarify family history and may necessitate testing of other family members. Since individuals' genetic information does not change over time, a specific genetic test only has to be performed once in their lifetimes. For these reasons, genetic tests and services have broadened the diagnostic and predictive capabilities of laboratory services and, in some cases, replaced older methods of diagnosis.

Genetic tests and services face many of the same integration challenges as other new medical technologies, such as building a sufficient evidence base that demonstrates they are similar or superior to existing technologies and services. Some of the same processes that have successfully allowed for the integration of other new medical technologies can contribute to ensuring the integration of genetic tests and services. However, genetic tests and services have certain characteristics that pose additional challenges to the current health care financing and delivery system that will need to be considered.

First, genetic services may involve a primary care provider **or nurse** to coordinate the patient's health care, a medical geneticist to assist with the diagnosis and treatment of diseases with a genetic component, a **nurse or** genetic counselor to educate and counsel the patient before and after genetic testing, a laboratorian to carry out testing, possibly yet another specialist to manage treatment of the condition, and allied health professionals to provide any necessary social support services. The involvement of multiple providers presents significant challenges for the appropriate coordination of care and coverage and reimbursement of these services.

ONS urges the Committee to be consistent throughout the document in term of its use of the term genetic counselor – genetic counselor refers only to masters prepared genetic counselors and does not include physicians, nurses, and other professionals trained in

genetics providing genetic counseling; as such, ONS strongly recommends that when referring to the cadre of professionals providing genetic services, including nurses, that a more generic term, such as genetics professional be used to be more inclusive.

Second, for many diseases, disease onset is the result of an accumulation of multiple risk factors. Genetic risk factors are one type of risk factor that has been identified for such complex diseases. No clinical interventions are currently available that modify the genetic mutation(s) that increases one's overall risk for the disease (although gene transfer strategies may make this possible in the future); however, knowing one's genetic risk through genetic testing can indicate whether certain individuals stand to benefit from taking steps (e.g., increasing physical activity, prophylactic surgery) that might not have been taken had genetic testing not been performed. For instance, individuals that are found to have the BRCA1 or BRCA2 mutation through genetic testing sometimes receive mammograms more frequently or at an earlier age than recommended for the general population, or choose to have a prophylactic mastectomy and/or prophylactic oophorectomy to reduce their chances of developing breast cancer and ovarian cancer. In this example, the gene, and therefore the genetic risk, is still present; however, the overall risk of disease onset is reduced because of these preventive measures taken.

Third, genetic tests are used not only to diagnose existing disease but also increasingly to assess genetic risk of future conditions. Many of these genetic tests capable of providing risk information are available for diseases for which no treatments or clinical interventions exist to modify this risk. For example, genetic testing for Huntington disease identifies individuals with close to a 100 percent risk of manifesting this disease. For individuals who test positive, there is no available therapy that can delay or prevent onset of the disease or alleviate symptoms once they manifest. Although there are no therapeutic options available, this information may still be useful for differential diagnosis and overall clinical management. Furthermore, for many people, knowing this information can be useful for family, long-term care, and estate planning purposes. Such information is also viewed by some as having value for personal well-being and overall health (psychosocial as well as physical).

Fourth, unlike many other laboratory tests, genetic tests raise complex legal, ethical, societal, psychological, familial, and personal issues. For example, genetic testing can raise concerns about privacy and confidentiality, genetic discrimination, reproductive options, social stigmatization, and personal and group identity. In addition, the rapid development of the science may lead to new discoveries that reveal new information about an individual based on previous test results, and this new information raises implications not previously considered. Because of these complexities, genetic counseling **often is** warranted to ensure that individuals are informed of the implications of their testing decisions and the limitations of the possible results.

Lastly, in the case of genetic tests for heritable mutations, an individual's test results can have implications for other blood relatives. At this time, there are no guidelines for balancing the provider's duty to warn family members of their genetic risk for heritable

These characteristics, combined with the increasing importance of genetics in clinical practice and public health, require a healthcare financing and delivery system that can respond quickly and responsibly, and that is well-equipped to provide and pay for genetic services and follow-up care appropriately, effectively, and in a coordinated manner.

nurses (including advanced practice nurses), medical geneticists, pathologists, and genetic counselors (as stated above, ONS recommends a consistent use of the term genetic counselor and a consistent more generic terminology to refer to the cadre of professionals providing genetics services; if naming specific health professionals, nurses always should be specified among the group of professionals providing such services).

- Test characteristics – the test sensitivity and specificity (analytical validity) should be considered as well as direct and indirect costs associated with the test, including induced costs such as additional provider visits[21,22]

Thus far, relatively few cost-effectiveness analyses have been conducted for genetic tests. Of those that have been performed, results have been mixed. Such results have often been sensitive to the prevalence of the genetic mutation in the population, disease characteristics, severity of outcomes, treatment costs and length, and accuracy of the genetic test.[23] The dearth of favorable cost analyses and deficiencies in the availability of data to inform such studies may be limiting health plans' willingness to consider coverage of genetic tests and services.[24]

Considering cost-effectiveness data as part of coverage decision-making has been controversial but is currently being considered in some areas of health policy-making. For example, the U.S. Preventive Services Task Force has begun reviewing published cost-effectiveness studies as part of its development of recommendations for clinical preventive services. Appropriately incorporating cost considerations in coverage decision-making requires answering hard questions about how cost-effectiveness data ought to affect decisions and what threshold of cost-effectiveness is appropriate.

ONS recommends that cost-effectiveness evaluation also should include/take into consideration the provision of the counseling services. Also, if a genetic test is positive for a certain condition, ONS urges public and private payors to provide coverage for and adequate reimbursement of the medically necessary follow-up and recommended procedures/treatments. ONS recommends that the SACGHS add these two items to its recommendations contained in this report.

[21] Higashi MK and Veenstra DL. Managed care in the genomics era: Assessing the cost effectiveness of genetic tests. American Journal of Managed Care 2003. 9(7): 493-500.

[22] Patients seeking genetic services frequently have medical problems that, depending on the test results and nature of the disease and test (e.g., presymptomatic, diagnostic), may require additional testing, more frequent periodic screening, or long-term treatment whose costs can be substantial. Thus, when costs are taken into consideration in coverage decision-making, it is important not only to consider the immediate costs of the genetic services (e.g., cost of the test and counseling) but also the costs associated with any follow-up care appropriate for the patient's circumstances. Not including these costs could result in a poorly informed coverage decision.

[23] Phillips KA and Van Bebber SL. A systematic review of cost-effectiveness analyses of pharmacogenomics interventions. Pharmacogenomics 2004. 5(8):1139-49.

[24] Of note, it is important to acknowledge the inherent limitations of the utility of cost evaluations and that there may be situations where they are either inappropriate or infeasible. For example, genetic testing for rare diseases, which are characterized by their low prevalence, likely would never be found to be cost-effective for broad screening purposes. However, such genetic tests clearly have value for medical management purposes and ought to be provided to those with a family history or specific disease symptoms.

(As noted above, ONS advocates recommending coverage of appropriate follow-up procedures/treatments necessary after a positive test result.)

Role of Consumer Demand. Despite the emphasis on evidence-based coverage decision making, consumer demand has been shown to also exert influence over coverage decisions. In instances where consumer demand is strong, health insurance plans have responded by reversing their decisions even when the evidence to support coverage was weak or non-existent.[25] With regard to genetic tests, direct-to-consumer advertising for such tests may be having an impact on consumer demand, especially given greater patient access to health information through the internet and other media.[26] **(ONS notes that cancer tests may be particularly vulnerable to this factor.)**

Evidence Base for Genetic Counseling Services. The value and effectiveness of genetic counseling services have been measured several ways in the literature. Various studies have shown increased knowledge, lower costs as a result of more appropriate use of genetic tests, and higher rates of risk identification as some of the outcomes of genetic counseling services.[27] Genetic counseling services provided by non-physician providers also can lead to cost containment since non-physician providers typically charge 20 to 50 percent less than physicians.[28]

Influence of Medicare on Private Plans. As the largest provider of health insurance in the U.S., Medicare's decisions are important to and monitored closely by private sector insurance plans. When Medicare decides to cover a service or test, the private market very often follows suit. It is not clear whether this reliance on Medicare's decision making is appropriate with respect to genetic tests. Genetic tests are often used for preventive purposes and can be used to inform reproductive decision-making and life planning. Many, if not most, hereditary diseases will manifest prior to age 65. For these reasons, the utility of many genetic tests and services (including predictive and predisposition genetic tests and genetic counseling) in the Medicare population is not straightforward. Since the patient population is a relevant factor in coverage decision making, it may not be optimal for the private sector to determine its coverage policies based on Medicare policy for genetic tests and services. Perhaps in realizing that Medicare policy may not be the most appropriate model, some health plans have not waited for Medicare's assessment prior to covering a genetic test or service.

Preliminary Recommendation

Standardization of coverage decisions using best scientific evidence across public and private payers is recommended.

[25] For example, even though there was a paucity of clinical evidence of efficacy, more than 41,000 patients underwent high-dose chemotherapy plus autologous bone marrow transplant for breast cancer in the 1990s. Intense political lobbying, the threat of litigation (exacerbated by a court decision in California that awarded $89 million to the family of a woman who was denied coverage for ABMT and eventually died from breast cancer), and several state and federal mandates caused many health plans to cover the treatment. (Mello MM and Brennan TA. The controversy over high-dose chemotherapy with autologous bone marrow transplant for breast cancer. Health Affairs 2001. 20(5):101-117)

[26] SACGHS wrote a letter to the Secretary in December 2004 requesting the HHS agencies conduct an analysis of the public health impact of direct-to-consumer advertising of genetic tests.

[27] A more detailed discussion of the value and effectiveness of genetic counseling services is provided in Appendix B.

[28] Gibons A. Employer-based coverage of genetic counseling services. *Benefits Quarterly* 2004, p.48-68.

Medicare Coverage

ONS has concerns about current Medicare policy being used as a benchmark for coverage of genetic tests since at this time most testing is done earlier in life for the purpose of prevention, diagnosis, and intervention and coverage for the nation's seniors is not necessarily appropriate or should be the standard for a younger population.

Although Medicare faces many of the same challenges as private health insurance plans, there are several that are unique to or experienced differently by the government program, including how coverage decisions are made and what services can be considered for coverage.

Role of Congress. When Medicare was established in 1965, Congress broadly outlined the scope of benefits that were covered by the program (see pp. 60-61 for benefit categories). Congress continues to have a role in defining the scope of benefits, as evidenced by the recent addition of prescription drug benefits.

Role of the Centers for Medicare & Medicaid Services. The Centers for Medicare & Medicaid Services (CMS) is responsible for interpreting and implementing Medicare law. More specifically, the agency determines whether specific services fall within the Congressionally defined benefit categories and decides whether to add a service to the scope of benefits. CMS also has a role in establishing and implementing policies that guide coverage decisions.

Medicare Coverage Advisory Committee. When a service to be considered for coverage is the subject of significant scientific, medical or public controversy, has the potential to have a major impact on the health of beneficiaries and/or the Medicare program itself, or raises important social, legal or ethical issues, CMS will seek the assistance of the Medicare Coverage Advisory Committee for additional expertise and public input.

Local Coverage Determinations. Medicare coverage decisions are made both at the local and national level, though the majority of Medicare coverage policy decisions are made by the 36 local contractors. This approach allows Medicare to be responsive to geographic variations in clinical practice and beneficiary needs and to extend coverage to new tests and services more rapidly than the national coverage process. Local coverage determinations (LCDs) can also help manufacturers collect necessary evidence to support a national coverage determination (NCD). LCDs are primarily based on expert medical opinion and empirical evidence. They apply only to the area that the contractor serves and must adhere to national statutes and regulations.

National Coverage Determinations. NCDs are made at the federal level and apply to all beneficiaries and carriers. National coverage review processes can be initiated internally within CMS or through a formal request from a member of the public. A review process may be initiated internally for many reasons, including if:

1) There are conflicting LCDs;

Greater consistency in Medicare coverage policy nationally is recommended and encouraged. (ONS notes that a more consistent approach would better facilitate integration.)

coverage policies can cause confusion and engender a sense of inequity among Medicare beneficiaries. Also, entering into the national coverage review process is not without risk in that the process can result in a non-coverage or limited coverage decision. In such cases, the NCD pre-empts any existing LCDs for the technology or service and prevents implementation of future LCDs. Also, Medicare decisions are closely followed by private health plans, so non-coverage decisions can also affect coverage by private health plans. Furthermore, while it is possible to appeal a non-coverage decision, it is an extremely lengthy process with multiple requirements.

FDA Approval Requirement. In order to be considered for coverage, tests under the purview of the Food and Drug Administration (FDA) must be FDA-approved. In the case of laboratory-developed genetic tests, which are not subject to FDA pre-market review, this criterion is not applicable. Genetic test kits that are packaged and sold commercially, on the other hand, are subject to FDA review and must be proven to be safe and effective for clinical use before CMS will consider coverage.

Reasonable and Necessary Requirement. Tests and services also must be shown to be "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. While there is no statutory or regulatory definition of reasonable and necessary, CMS has interpreted the phrase to require that the item or service should, at a minimum, improve net health outcome for Medicare beneficiaries who would receive the item or service. To reach a conclusion, CMS uses standard principles of evidence-based medicine, which requires a thorough evaluation of relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of reasonable and necessary.[1] The assessment of clinical evidence is divided into three stages:

1) Quality of the individual studies;
2) Relevance of findings from individual studies to the Medicare population; and
3) Overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the technology's risks and benefits.

Possible Outcomes of Coverage Decision-making Process. The following are possible outcomes of the policy decision-making process:

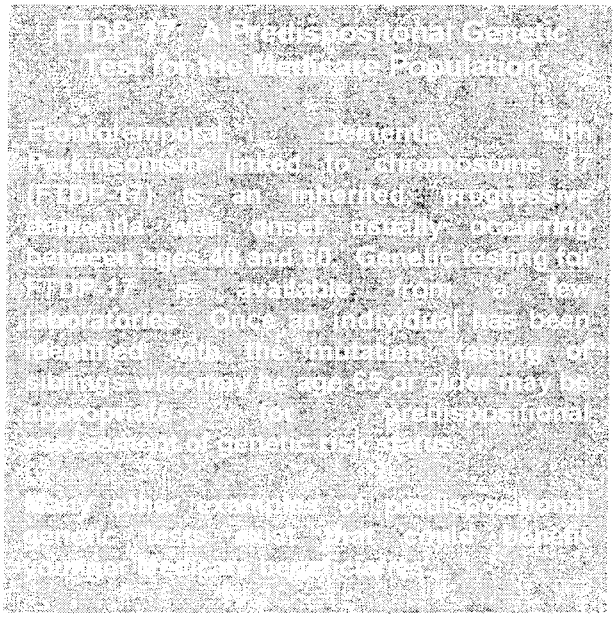
1) A national coverage decision is issued with limitations on coverage;
2) A national coverage decision is issued with no limits on coverage;
3) A national non-coverage decision is issued precluding local contractors from making payment; or
4) No national decision is issued, leaving coverage to the discretion of the local contractor.

Medicare Coverage of Genetic Tests. Of the approximately 274 national coverage decisions issued by CMS, only one relates to genetic tests and services -- cytogenetic analyses for monitoring acute leukemia, myelodysplasia, and congenital abnormalities. A few local Medicare coverage policies have been developed for HER-2/*neu* and BRCA testing. However, for BRCA testing in the absence of signs, symptoms, or personal history of the disease, most local contractors do not cover the test because they consider it to be a screening test, which CMS has interpreted not to be a statutory benefit.

Screening Exclusion. In order for Medicare to cover a service or technology, it must fall within one of the statutorily authorized benefit categories. Items and services that do not fit within one of the benefit categories prescribed by Congress are not reimbursable.

CMS has a long-standing policy that states that "tests that are not reasonable and necessary for the diagnosis or treatment of an illness or injury are not covered"[30] and more specifically, that "tests for screening purposes that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered *except as explicitly authorized by statute.*"[31] This policy is largely based on an interpretation of statutory language that includes coverage of expenses that are "reasonable and necessary for the diagnosis of illness or injury or to improve the functioning of a malformed body member"[32] and that excludes coverage of expenses "for routine physical checkups, eyeglasses, or eye examination, ...hearing aids or examination."[33] The preventive screening tests that Medicare does cover have been legislatively authorized by an act of Congress on a service-by-service basis.

Application of Screening Exclusion to Genetic Tests. Since predictive and predispositional genetic tests are considered to be screening tests performed in the absence of signs, symptoms, complaints, or personal history of disease or injury, they are not covered under Medicare statute. Diagnostic genetic tests, on the other hand, can be covered under Medicare because they are performed in the presence of signs and symptoms of disease. **Some cancer tests are prognostic which assist with diagnosis, treatment, medical management, health care planning, etc. and as such should be covered.** Pharmacogenetic tests that are performed in the presence of signs, symptoms, or a personal history of disease or adverse drug reactions **should** be covered under Medicare. However, it is not clear whether pharmacogenomic testing using microarrays (e.g., Roche's CYP450 AmpliChip) to test



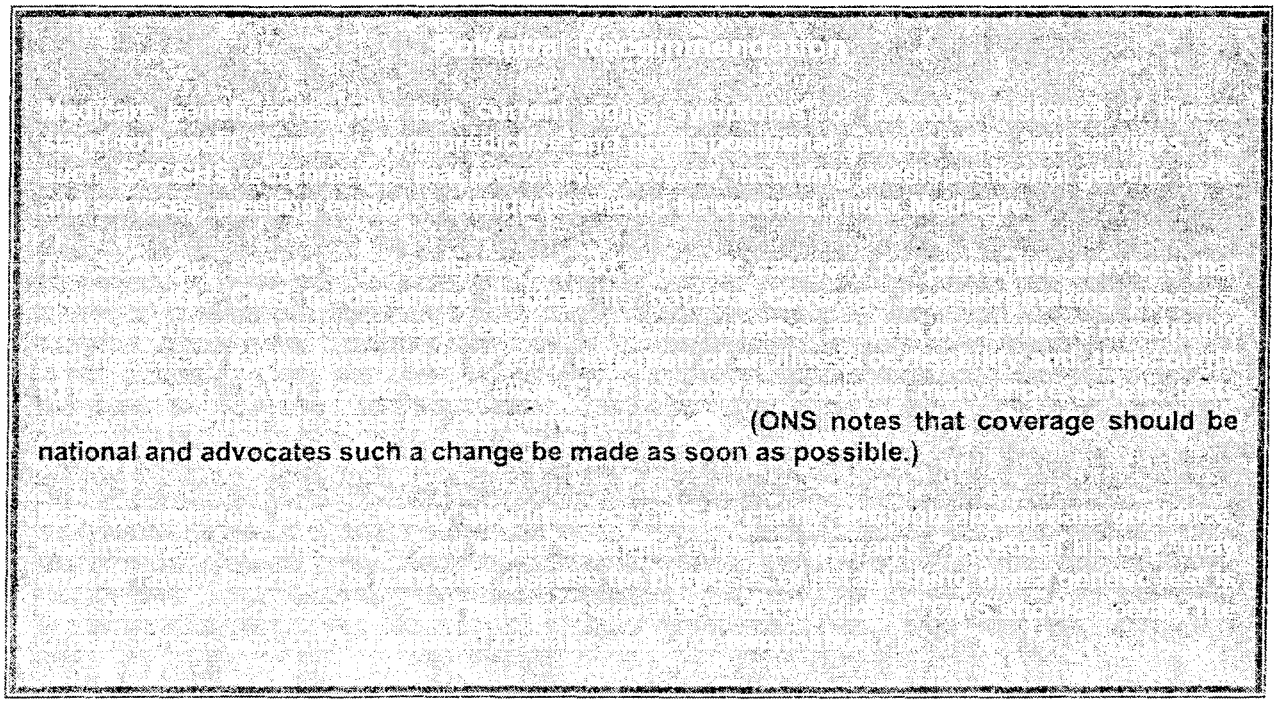
[30] For example, see 66 FR 58813
[31] 42 USC 1395y(a)
[32] 42 U.S.C. §1395y
[33] Ibid.

several different drug-metabolizing genes for a large variety of single nucleotide polymorphisms (SNPs) at one time would be covered since these genes and SNPs may not all be informative with respect to the treatment of the disease at hand. Pharmacogenomic testing used as a screening tool (in the absence of signs, symptoms, personal history, or complaints of disease) to help guide drug therapy decisions probably would not be covered under Medicare.

Application of Screening Exclusion to Genetic Counseling Services. Reimbursement by Medicare for genetic counseling is also limited by the program's screening exclusion. Much of genetic counseling involves discussions with patients who have a strong family history of disease; however, family history of disease does not meet Medicare's reasonable and necessary criterion. Therefore, Medicare does not cover genetic counseling accompanying a predictive or predisposition genetic test in the absence ofsigns, symptoms, or personal history of disease.

ONS notes that these exclusions are problematic and advocates that changes be made to the current Medicare statute to ensure coverage for the full range of appropriate genetic tests and associated counseling for all beneficiaries in need.

Increasing Receptiveness to Coverage of Preventive Services. Recent discussions in both Congress and throughout HHS suggest that policy makers may be growing more receptive to the idea that the Medicare program should broaden its coverage of preventive services. In the past two decades, Congress has authorized Medicare coverage for several screening tests and services (e.g., mammography). The enactment of the Medicare Prescription Drug, Modernization, and Improvement Act of 2003 reflects an increasing focus on prevention. Congress also authorized several demonstration projects in disease management. Given the potential role for preventive and/or diagnostic genetic tests in disease management, there may be an opportunity to include them in these ongoing demonstration projects.



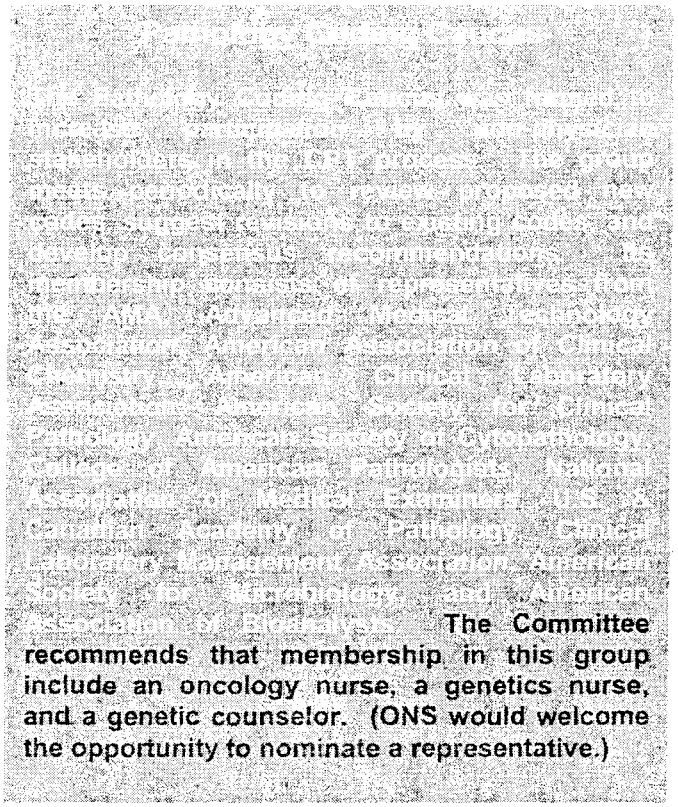
(ONS notes that coverage should be national and advocates such a change be made as soon as possible.)

In contrast to Medicare, whose NCDs guarantee coverage for a service from that point forward (unless it is subsequently modified), Medicaid benefits that go beyond the federal requirements can be scaled back or dropped at any time by states, and eligibility requirements can be made more stringent. The balanced budget mandate creates instability in the level of coverage states can provide for health services and tests. Even if a state decides to add a new genetic test or service to its benefit package one year, it could be dropped the next. States' fiscal policy thus makes it extremely difficult to secure access over the long term to new tests and services for the Medicaid population.

(ONS notes that ideally coverage for genetic tests and counseling under both Medicare and Medicaid should be provided and should be the same to avoid a two-tiered system. ONS further notes that since there is no minimum coverage for genetic testing/counseling under Medicaid this poses a significant barrier to equal access to genetic testing. ONS recommends that the Committee be specific in advocating a more standardized approach to coverage and reimbursement to ensure access to care across payors.)

Current Procedural Terminology. Created in 1966 by the American Medical Association (AMA), the CPT coding system is a listing of standard descriptive terms and identifying codes for reporting medical services and procedures to public and private health programs. CPT codes consist of a 5-digit number that is associated with a brief description of the procedure.

CPT Editorial Panel. CPT codes are updated annually by the AMA CPT Editorial Panel. The CPT Editorial Panel is responsible for revising, modifying and updating CPT codes as new and emerging tests are developed and replace outmoded procedures. The Panel will consider adding a new code or code change if it: 1) is for a distinct clinical service performed throughout the U.S.; 2) is provided or supervised by physicians or other type of health professional; and 3) does not duplicate or fragment existing codes. Panel decisions include: 1) approval of a new code; 2) revision of existing nomenclature; 3) tabling of a proposal until further information is obtained; or 4) rejection of a request.



The Committee recommends that membership in this group include an oncology nurse, a genetics nurse, and a genetic counselor. (ONS would welcome the opportunity to nominate a representative.)

CPT Codes for Genetic Tests. Genetic tests are billed using pathology and laboratory codes (see page 41 for listing of genetic test CPT codes). The CPT codes used for billing genetic tests are not specific to the condition being tested; rather, the code identifies the procedure used (e.g., reverse transcription). Usually several codes are used when billing for genetic testing that reflect the multiple steps involved in genetic testing.

Because CPT codes for genetic tests are procedure-based, a new genetic test performed using existing procedures does not result in the development of a new CPT code. Thus, the payment amount for a new genetic test will be based on the reimbursement amounts associated with existing CPT codes.

CPT Code Modifiers. If existing coding systems are not sufficiently descriptive of the service being provided and the reason it is being provided, it can be difficult for health insurance plans to process the claim appropriately and efficiently. There is some anecdotal evidence that the current 5-digit codes available for billing genetic tests and services are not specific enough to allow health insurance plans to make informed claim determinations. As a result, claims are denied, recoded, or referred back to the provider for additional information. If claims for genetic tests and services are repeatedly denied due to inadequate codes, providers and laboratories may become less willing to offer

these tests and services or to accept third-party reimbursement. In such situations, costs may be transferred to patients who are unable to pay for the test and services may become inaccessible.

Last year, a Genetic Test Coding Workgroup[36], a consortium of genetics and laboratory organizations, submitted a proposal to the CPT Editorial Panel requesting the addition of 2-digit modifiers to supplement the existing 5-digit CPT laboratory codes used for genetic testing. AMA adopted these modifiers and included them in Appendix I of *CPT 2005*, its annual listing of current CPT codes. The first numeric digit indicates the disease category, and the second alpha digit denotes gene type (see pages 41-43 for list of genetic testing code modifiers). These modifiers convey important information to health insurance plans about the nature of the test being billed so that they may better assess whether the test is covered by the patient's policy. They will not, however, change reimbursement rates for these codes.

It is anticipated that these modifiers will be less prone to being denied payment and will allow for better tracking of utilization of genetic tests according to gene type and disease category. Initial reaction by health insurance plans to the modifier codes has been mixed, however, with some plans discouraging their use, stating that, if claims using these modifiers are submitted, the claim will be denied.

Category III CPT Codes. To facilitate the collection of data for new and emerging technologies and services, a separate set of CPT codes are available for tracking purposes. These category III codes are used to help substantiate widespread usage or obtain pre-market approval by the Food and Drug Administration but are reimbursed less frequently, especially by private plans. These codes are particularly appropriate for novel genetic technologies and testing procedures, but they are not useful for new genetic tests that use existing technologies and laboratory procedures for which a CPT code exists. **(ONS notes that its nurses report that much confusion exists across the country regarding what codes to use.)**

CPT Codes for Genetic Counseling Services. Genetic counseling services are billed using evaluation and management (E&M) CPT codes. Like the genetic testing CPT codes, E&M codes used for billing genetic counseling services are not specific to genetic services; rather, they are generic codes used by all specialty types for patient visits. The codes are grouped into four categories: 1) consultation codes for patients referred by another physician; 2) office visit codes for self-referred patients; 3) preventive medicine/risk reduction codes for services provided to promote health and prevent illness or injury; and 4) health behavior and assessment codes for services associated with acute or chronic illness, prevention of a physical illness or disability, and maintenance of health provided by non-physicians (see page 44 for list of genetic counseling CPT codes).

Determinations about which E&M code to use are based on the amount of time spent face-to-face with the patient, in addition to several other factors (history, physical examination, medical decision-making, counseling, coordination of care, and the nature of the presenting problem). The highest level E&M code available (level 5) is for an 80-

[36] The Genetic Test Coding Workgroup is distinct from but its membership overlaps with the Pathology Coding Caucus described in box on page 38.

minute visit (many genetic counseling visits can last two hours or longer). Prolonged service codes are available if the services are beyond those normally provided; however, health plans generally do not reimburse for these codes. Using multiple codes or using codes multiple times for the same visit to account for the additional time spent is not permitted.

Planned Revisions to E&M Codes. In response to problems with documentation of provided services in the medical record, the CPT Editorial Panel had begun taking steps to revise the E&M codes to better reflect current clinical practice. Initially, a work group of the Panel tasked with devising a new E&M coding system had concluded that current codes would be kept as is but proposed modifications to the criteria used in determining the appropriate code.[37] The next phase was to have been development of specialty-specific clinical examples to assist providers in selecting the appropriate code using the new criteria; however, the task was unsuccessful in a pilot test. Instead, AMA will be addressing the documentation problem by developing educational resources that provide clinically relevant information on how to appropriately use E&M codes.

Previous to this recent effort, the CPT Editorial Panel considered proposals for the creation of CPT codes for family history/risk assessment/pedigree analysis. **(ONS notes that such codes would be useful especially with the expectation that the use of genetic tests is expected to increase. ONS urges the adoption/implementation, use, and reimbursement of such codes.)** These proposals were tabled at the time due to the planned revisions the E&M coding system. Because these revisions were not made, the American College of Human Genetics plans to resubmit its proposal at a future date for reconsideration by the CPT Editorial Panel.

E&M Code Relative Values. The AMA, through its Relative Value Scale Update Committee, assigns each E&M code a relative value. The relative value assigned to each E&M code is based on the time it takes to perform the service, the technical skill and physical effort, the required mental effort and judgment, stress due to the potential risk to the patient, practice expense, and professional liability insurance. The relative values are updated each year to account for changes in medical practice.

CMS uses this relative value to determine Medicare payment rates for E&M codes. Medicare payment rates for E&M codes are calculated by multiplying the relative value by a monetary amount that is determined by CMS. These payment rates are then adjusted for geographical differences in resource costs.

[37] Report of the AMA Board of Trustees. Process for the Development of Clinical Examples for the Proposed New CPT Evaluation and Management (E&M) Codes, 2003. http://www.ama-assn.org/ama1/upload/mm/annual03/bot30a03.doc.

- The local payment amount is grossly higher or lower than the local payment provided by other purchasers in the same locality[41]

inherent reasonableness could provide a way to address instances of extreme under-reimbursement and payment variation among localities for genetic test codes. However, the review process requires a significant amount of data collection and analysis and, as an incremental approach, may result in a lower rather than a higher payment rate. Nonetheless, this mechanism might be used to temporarily redress extreme discrepancies between cost and payment for the CPT codes used for genetic tests until the laboratory fee schedule freeze is lifted.

Public Comment

(ONS notes that improvements to the coding and reimbursement system are much-needed to help ensure and improve access to genetic testing.)

Clinical Diagnostic Laboratory Test Regulations. In an effort to increase the transparency of its rate setting process for new clinical diagnostic laboratory tests and in order to comply with Section 942(b) of the Medicare Drug Prescription, Modernization and Improvement Act of 2003, Medicare will be establishing regulations that outline "procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005."[42] These regulations will not affect already existing HCPC codes, including those currently used to bill for genetic tests.

Billing and Reimbursement of Genetic Tests

Payment Rates for Genetic Tests. Like coverage policies, payment rates are considered proprietary, making it difficult to empirically assess the adequacy of reimbursement for genetic tests and services. However, Medicare's Clinical Laboratory Fee Schedule, which is available to the public, is used by health plans throughout the U.S. as a baseline for the development and negotiation of their own fee schedules, making it a logical resource for comparing payment rates with actual costs for genetic tests in both the public and private sector.

In 2002, Medicare reported spending $13 million on 270,000 claims for genetic tests (approximately $48 per test).[43] Testimony provided to SACGHS in March 2004 showed

[41] Testimony of Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services. Medicare Payment for Medical Supplies. Senate Appropriations Labor, Health and Human Services, and Education Subcommittee. June 12, 2002. http://www.cms.hhs.gov/media/press/testimony.asp?Counter=635.
[42] Public Law 108-173.
[43] Sean Tunis, Medicare Coverage and Genetic Testing. Presentation to SACGHS on March 1, 2004. http://www4.od.nih.gov/oba/SACGHS/meetings/March2004/Tunis.ppt.

GNCC also offers a genetics clinical nurse credential for non-master's prepared nurses.[53]

ONS notes that the GNCC information on its website specifies 300 hours of genetic practicum, log of 50 cases within five years of the application, and four written case studies reflecting ISONG standards. ONS urges that this section be reviewed for accuracy as the statement of three years of experience appears incorrect. The GNCC website does state the requirement that an applicant's CV reflect three years of active membership in a related professional association committee. www.geneticnurse.org.

ONS urges that when speaking of competencies, the Committee should acknowledge that knowledge of the disease – e.g. cancer – is as essential and as important as the understanding of genetics.

As the number of clinical relevant genetic tests rises, ensuring access to both tests and genetic counseling services will become increasingly important. Patients' access to genetic counseling services may be limited by a provider's inability to obtain a provider identifier number, lack of licensure, and inadequate payment and CPT codes.

Billing for Genetic Counseling Services. Payment rates for genetic counseling services can vary depending on how they are billed. Genetic counseling services can be billed either using generic CPT E&M codes or, if provided by a hospital employee, as part of the hospital facility fee. The lack of specific codes for genetic counseling services can be problematic due to the nature of these services as compared to regular provider visits. Specifically, genetic counseling sessions can last 2 to 3 hours, not including the often extensive time spent preparing for a counseling session and following up with the patient; however, the highest-level CPT E&M code available for billing for these services accounts for a significantly shorter timeframe. Prolonged service codes are available but are infrequently reimbursed.

ONS notes that insufficient reimbursement or the lack of payment altogether is one of the major barriers and that adequate coverage and reimbursement would help ensure access to high quality, appropriate care for patients in need of such testing and services.

Billing Medicare. Under Federal regulations, physicians and, to a limited extent, non-physician practitioners licensed under state law to perform a specific medical procedure without physician supervision are able to directly bill Medicare.[54] Nurse practitioners, physician assistants, certified nurse specialists, certified nurse midwives, clinical psychologists, and clinical social workers are non-physician practitioners statutorily eligible to directly bill Medicare.

Auxiliary personnel provide care under the physician's direct supervision and bill for their service as "incident to" the supervising physician or hospital. Auxiliary personnel include nurses, non-physician anesthetists, psychologists, technicians, therapists, and other aides. Direct supervision of auxiliary personnel requires the physician to be present in the office suite and immediately available to furnish assistance and direction

[53] Genetic Nursing Credentialing Commission. Genetic clinical nurse requirements and information. http://www.geneticnurse.org/APNG.htm.
[54] 42 CFR Ch. IV§410.20

(but (s)he does not need to be present in the room) throughout the performance of the procedure.[55]

With respect to genetic counseling services, if a service is billed incident to a supervising physician, the physician only may utilize the 99211 E&M code (used for billing for 5-minute visits with minimal problems present) to seek reimbursement for the genetic counseling service.[56]

Billing Private Health Insurance Plans. The ability of health professionals to directly bill private health plans directly depends on provider type, scope of practice, the provider's employer, the policies of the health plan and the state in which the service is provided. Physicians are generally able to bill directly for genetic services as long as they fall within their scope of practice. Non-physician providers generally bill through a supervising physician unless the state recognizes their profession as capable of practicing independently and health plans permit them to directly bill for their services. Fifty-seven percent of genetic counselors responding to the 2004 Genetic Counselor Professional Status Survey conducted by the National Society of Genetic Counselors billed through their supervising physician, 9 percent bill in their and their supervising physician's name, and 2 percent bill in their name only.[57]

Services of non-physician providers employed by a hospital may be billed as part of the hospital's facility fee or as part of their unit's comprehensive fee, which is determined as part of the hospital's contract with the health plan. Eight percent of genetic counselors billed through the facility fee and another 6 percent had their bill included in the comprehensive fee.[58]

ONS notes that some plans do not and will not recognize nurses who provide genetic counseling but they do/will recognize genetic counselors. This limitation can have an adverse impact on patient access to necessary care and counseling. ONS urges that all payors – public and private – recognize and reimburse for genetics services provided by qualified health professionals, including nurses. The Committee should be explicit in making and repeating this recommendation.

ONS urges that all wording in this report related to both public and private payor coverage and reimbursement of genetic services be inclusive of all health professionals providing genetic counseling and testing services and not be limited to only board certified medical geneticists and genetic counselors.

Billing Medicaid. State Medicaid programs follow billing practices similar to Medicare and private health insurance plans; however, some states have taken steps to facilitate direct billing by certain non-physicians. For example, Washington's Medicaid and Maternal Child Health programs have begun credentialing genetic counselors as service providers so that they can bill the state's Medicaid program directly for their services. In Ohio, board-certified genetic professionals have been deemed by the state's Medicaid

[55] Medicare Carrier Manual Section 2050.1(B)
[56] Personal communication with CMS official
[57] National Society of Genetic Counselors, 2004 Professional Status Survey. http://www.nsgc.org/careers/2004_PSS_Final_pw.pdf.
[58] Ibid.

program as appropriate providers of medical genetic services and may bill Medicaid directly for their services.

Provider Identifiers. All physicians and specified non-physician practitioners allowed to directly bill Medicare are required to have a Unique Provider Identifier Number (UPIN). Because auxiliary personnel are not permitted to bill Medicare directly for their services, they are not eligible for a UPIN.

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) mandated the adoption of a uniform unique health provider identifier for all healthcare providers, not just Medicare providers, for use in standard electronic transactions. In compliance with the HIPAA administrative simplification provisions and in an effort to remedy the limitations of the UPIN system, CMS is expected to implement the National Provider System (NPS) incrementally as a replacement to the UPIN system. CMS issued final rules on a National Provider Identifier (NPI) in January 2004.[59] Once NPS is implemented in 2006, all public and private health plans, healthcare clearinghouses, and health providers who are licensed, certified, or otherwise authorized to perform medical services or medical care, equipment, and/or supplies in the normal course of business must begin using the NPI (small health plans will have an additional year to comply). Auxiliary personnel (e.g., nurses, genetic counselors) not currently eligible for a UPIN but that are able to bill some health insurance plans directly will be eligible to receive an NPI. However, NPI eligibility would not affect their current ineligibility to be directly reimbursed by Medicare nor would it guarantee payment for genetic counseling services.

ONS urges that non-physician health professionals and auxiliary personnel be eligible for and given an NPI.

State Licensure. The purpose of licensure is to ensure quality and safety of health services. In many states, only health providers licensed by the state may legally bill for health services, and many health insurance plans require health providers to be licensed in order to be credentialed as one of their network providers.
State licensure programs are available for most health professions that provide genetic counseling services, with the exception of genetic counselors. Currently, only three states - Illinois, California and Utah - have passed legislation authorizing licensure of genetic counselors (only Utah has implemented the law), and 10 other states have introduced bills or are in the process of drafting bills that would establish licensure for genetic counselors.[60] Some of the reasons cited for not enacting licensure for genetic counselors include lack of evidence demonstrating harm to consumers in the absence of licensure, insufficient evidence demonstrating a need for licensure, concerns that other practitioners could be adversely affected or that patient access to genetic counseling providers would become restricted or reduced, and in some states with few genetic counselors, the high programmatic costs relative to the number of genetic counselors in the state. While state licensure does not guarantee reimbursement[61], it is expected to

[59] FR Notice of Final Rule on HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers. http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-1149.pdf.
[60] Colorado, Florida, Massachusetts, New York, New Jersey, Texas, Washington and Wisconsin are currently considering or drafting bills that would enable licensure of genetic counselors.
[61] Other factors in addition to licensing may influence a provider's ability to participate in a health plan's provider network, including the provider's accessibility (e.g., scheduled office hours) to plan members, the health plan's provider needs,

improve genetic counselors' ability to be recognized as qualified providers of genetic counseling services and, thus, to increase their prospects of being reimbursed for their services. Preliminary evidence from Utah has credited the establishment of licensure with increasing payer recognition of the profession in terms of being allowed to bill incident to a physician, fewer payment denials, and an increase in the state's genetic counseling workforce.[62]

ONS has concerns that some licensure bills are written in such a way that nurses may not provide genetic counseling services without being licensed under the genetic counselors statute as genetic counselors, nor may nurses use the title genetic counselor or any similar title, even if they are credentialed in genetics or educated at the masters or doctoral level in genetics. Some bills being proposed at the state level (e.g. Massachusetts) have the potential for restriction of nursing practice of genetic counseling and title restriction. ONS does not support such restrictions and imposition on/interference with nursing scope of practice. ONS urges the Committee to make clear that state licensure bills for genetic counselors should not interfere with or in any way restrict nursing scope of practice (or scope of practice for other health professionals).

professional liability insurance, the sufficiency of health plan personnel, the system's ability to contract with and incorporate new providers, and, in the case of non-physician providers, the availability of a contracted supervising physician.

[62] Cantrell M. Life after licensure: Our office's reimbursement experience. Presented at NSGC Annual Education Conference, October 2004.

- that includes the direct involvement of relevant professional organizations and societies –

  (ONS notes that this should be based on criteria determined through the current professional organizations providing credentialing and those having a stake in the process because of their specialty knowledge base – e.g. ONS.)

- ONS urges that this recommendation also reflect the need for adequate reimbursement levels to ensure access.

(ONS again notes an inconsistent use of terminology – here non-physician health provider is used and the next bullet down uses "non-physician health professionals" – ONS urges the Committee to be consistent in its use of terminology throughout the report.)

ONS notes the absence of any discussion in this section of credentialing by physicians doing genetics and genetic counseling. Is it assumed that all physicians are trained in genetics and able to provide appropriate genetic counseling? ONS urges the inclusion of recommendations regarding criteria to determine competencies for physicians as well as non-physicians providing these services.

Broader Issues

Three other broad issues—health disparities, education and training of providers, and public awareness—warrant some discussion because of the effect they may have on the gathering and dissemination of information to decision makers and, in turn, coverage decision making.

Health Disparities

Disparities in health and health care exist among various segments of the population, categorized according to differences by gender, race/ethnicity, education/income, disability, geographic location, and sexual orientation. Health disparities have a number of causes, including underutilization of health services in particular groups. For example, differences in the use of angioplasty to treat coronary artery disease have been documented by gender and race. When new tests are not utilized as indicated in all appropriate populations, data about the utility of the test will be incomplete and inaccurate, and may result in flawed coverage and reimbursement decisions. If data on the use of a genetic test in a particular group are insufficient due to underutilization, adequate evidence justifying coverage of that new genetic test or service may be lacking and result in non-coverage for that particular group. This may exacerbate existing disparities in care.

In the future, drug development based on pharmacogenomics may help guide drug therapy decisions and improve the efficacy and safety of drug treatment. However, as more drugs are developed based on genotype, some individuals (those with other genotypes) may have limited access to new and effective drugs. This could result in an exacerbation of the health disparities problem. It is also likely to provide new challenges to health insurance plans in determining which drugs to cover and include on their list of preferred drugs. It may be difficult to find the right balance between providing access to the most effective drug based on genotype and providing access to drugs for the largest number of people.

A large multi-dimensional, population-based research study on the interactions between genetics, the environment, and disease could generate information that may inform clinical practice in such a way as to reduce or minimize existing health disparities and would facilitate evidence-based coverage decisions. SACGHS will be conducting an in-depth exploration of large population studies aimed at understanding the relationship

(does this term here mean to include a range of health professionals – physicians, nurses, etc.? if so, that should be specified)

(ONS notes that perhaps NCHPEG might be appropriate to mention here. In addition, ONS suggests that training and education for medical directors and case managers be included and addressed in this recommendation.)

between gene and the environment and their effect on health outcomes, which will inform any future recommendations on this topic.

Provider Education and Training

Demand by health providers for clinical use of, and thus coverage and reimbursement for, new genetic tests will be affected by their education and training in genetics and genomics. Genetics education and training should be a multi- and inter-disciplinary process since all health professionals need to be involved in delivering genetic medicine. This education will be incorporated throughout the course of training so that health providers are able to judge the merits of new genetic tests as they appear.

Increasingly, genetic tests are being marketed to health providers **and other health professionals such as nurses, social workers, psychologists, etc.** (and directly to consumers). **(ONS notes that the use of providers is inconsistent and urges consistent use and a clear definition of the term throughout the document).** If providers are not adequately trained in genetics, they may provide – and expect coverage for— inappropriate services on behalf of their patients. Adequate genetics education and training should enable providers to help their patients make decisions about when genetic tests and services are appropriate and discourage their inappropriate use.

Genetics education is also important for those who make coverage decisions. These individuals, who are often physicians, need an understanding of genetics to make accurate and informed coverage decisions for new genetic tests. **(ONS notes that it is important to ensure that all professionals providing genetic counseling services be trained and competent to provide such services. ONS appreciates the recognition here that it should not be assumed that all physicians are able to provide appropriate, competent genetic counseling.)**

Public Awareness

Public awareness of new health care tests and treatments can create consumer demand. For example, the trend toward less managed care demonstrates the influence of consumer demand, as does increasing utilization of prescription drugs. Pressure on

third-party payers from consumer demand can also have an impact on coverage and reimbursement decisions by health insurance plans.

Education can empower consumers in relation to payers. A decision influenced by consumer demand may be appropriate when this demand is based on valid and complete information. However, consumer demand can also be based on inaccurate and incomplete information. In these cases, consumers may demand coverage of services that have not been deemed to be safe, effective, or appropriate methods of treatment. For example, consumer demand contributed to health insurance plans' decisions to cover autologous bone marrow transplants for breast cancer even though there were questions raised about the safety and efficacy of this treatment. Consumers may also demand coverage for services whose medical necessity is questionable (e.g., drugs for erectile dysfunction). Although providing such services may improve quality of life, its health value is less obvious, as is the obligation of a health insurance plan to provide coverage.

With respect to new genetic tests, public awareness and consumer demand could play an important role in facilitating coverage for new, safe, efficacious, and appropriate interventions. Appropriate and timely coverage of new genetic tests could help to facilitate and speed the broad translation of genetics into healthcare, improving health outcomes, quality of care, and access to care. However, the complexity of genetics increases the risk of misinformation informing public awareness and fueling consumer demand. Media coverage has an important role in educating the public about genetic advances and communicating their relevance to health and health care of individuals in a manner that is understandable to laypersons. Furthermore, basic genetics education at the K-12 level may be important in providing a foundation for genetic literacy and public understanding.

Since genetics will have broad social impact, the role of public awareness and consumer demand with respect to coverage of genetic tests may be unique in relation to other healthcare tests. For this reason, consumers may have an important role in coverage decisions.

how to collect/gather and understand

how to collect/gather and understand

ONS notes that individuals and families should be directed to their health care providers in all of these communications and the recommendation should be modified to reflect this referral component.

counselors, with an additional 466 eligible for the 2005 examination cycle. ISONG reports 39 individuals credentialed as either an advanced practice nurse in genetics (APNG) or a genetic clinical nurse (GCN). Thirty ISONG nurses are also board-certified in genetic counseling. Overall, there are currently 3,076 professionals in the United States who are specifically trained, certified and dedicated to provide genetic counseling and clinical genetics services, of which 59 percent are Master's level genetic counselors. The number of physicians presenting for clinical genetics training (in either residency or fellowship) has been declining since 1996 according to data presented at the Banbury Summit on Genetics Training held in October 2004. In contrast, the numbers of genetic counselors trained has been increasing steadily during the same time period.

Training, Qualifications and Credentials of Providers of Genetic Counseling Services

Coverage and reimbursement depends on the qualifications of the providers. This section will detail the credentials and qualifications of genetics professionals.

The genetic counseling process involves the collection and interpretation of family, genetic, medical and psychosocial history information. **(ONS notes that physicians and nurses every day collect and interpret family, genetic, medical, and psychosocial history information. This definition of the "genetic counseling process" needs to be very clear and the wording is important. This should not mean that every physician or nurse collecting a family history or psychosocial information must be a genetics professional.)** Analysis of this information, together with an understanding of genetic principles and the knowledge of current technologies, provides patients and their families with information about risk, prognosis, medical management, and diagnostic and prevention options. Information is discussed in a client-centered manner while respecting the broad spectrum of beliefs and value systems that exist in our society. The genetic counseling process ultimately facilitates informed patient decision-making and promotes behaviors that reduce the risk of disease. As will be described later, the training needed to competently provide genetic counseling is specialized and includes coursework and hands-on supervised clinical experiences. This combination of coursework and clinical training distinguishes these individuals from other health providers who may occasionally provide genetic information.

ONS again notes that knowledge of genetics and the specialty in which someone is practicing both are very important. Genetics is sub-specialized and all health professionals providing genetics services should have a background in genetics but also in the specialty in which they practice. In cancer genetics, a background in oncology may be more relevant to assisting with genetic testing decision making than a background in genetics. A prenatal genetics professional without an oncology background would not necessarily be an appropriate person to provide cancer genetic counseling to a cancer patient. ONS urges the Committee to be specific in acknowledging this point.

Medical groups and organizations are beginning to recognize the importance of ensuring that qualified health professionals provide genetic counseling services. The National Cancer Institute has established a Cancer Genetics Services Directory that only includes the names of health providers who have met specified criteria and therefore are felt to be competent providers of genetic services.[72] Another example is the Minimum Guidelines for the Delivery of Prenatal Genetics Services, published by the Great Lakes Regional Genetics Group. These recommendations specify that "an ABMG-certified or eligible MD or PhD clinical geneticist or an ABGC-certified or board-eligible genetic counselor is available for consultation or case review" and that non-certified individuals should be supervised by a geneticist or genetic counselor.[73]

Training and Credentialing for Master's Level Genetic Counselors. In 1969, the first graduate program to specifically train genetic counselors to provide genetic counseling was established at Sarah Lawrence College. Training program guidelines were subsequently established and included course work in counseling theories and techniques, human and medical genetics, molecular biology and genetic counseling. Extensive supervised clinical training is considered an important component of genetic counselor training.[74]

ABMG was established in 1981 to certify MD and PhD geneticists, Master's trained genetic counselors, and nurses with a Master's degree and concentrated training in genetics. Eligibility for genetic counselor certification included a Master's degree in a relevant discipline and a logbook of 50 cases obtained at approved clinical sites. 631 genetic counselors were originally certified by ABMG.

In 1992, the American Board of Medical Specialties recognized ABMG, and as a result, genetics residency programs were established and accredited by the Accreditation Council for Graduate Medical Education. ABGC incorporated in 1993 and took over certification process for Master's level genetic counselors. 495 individuals with ABMG certification became charter members of ABGC. Individuals who did not meet the eligibility criteria to take the certification exam could apply to do so under special considerations through the 1999 exam. This mechanism allowed health professionals such as nurses and social workers who were experienced in providing genetic counseling but had non-traditional training to become certified by ABGC. The credentialing of PhD trained medical geneticists remained with ABMG.

ABGC also began, for the first time, accrediting genetic counseling graduate programs. Practice-based competencies that define the role of a genetic counselor were established.[75] They include four domains: 1) communication skills; 2) critical-thinking skills; 3) interpersonal, counseling and psychosocial assessment skills; and 4) professional ethics and values. The accreditation criteria for training programs were based on the program's ability to develop these competencies in its graduates. Although

[72] National Cancer Institute. Cancer Genetics Services Directory: Criteria for Inclusion. http://www.cancer.gov/forms/joinGeneticsDirectory.

[73] Sommer A, et al. Minimum guidelines for the delivery of prenatal genetics services. The evaluation of clinical services subcommittee. Great Lakes Regional Genetics Group. *Genet Med* 1999. 1(5):233-4.

[74] Walker AP, et al. Report of the 1989 Asilomar Meeting on Education in Genetic Counseling. Am J Hum Genet 1990;46:1223-30.

[75] Fiddler MB et al. A case-based approach to the development of practiced-based competencies for accreditation of and training in graduate programs in genetic counseling. *J Genet Counsel* 1996. 5:105-12.

each program's curriculum and method of supporting the development of the practice-based competencies is unique, programs must provide instruction in the following general content areas: 1) principles of human, medical and clinical genetics; 2) psychosocial theory and techniques; 3) social, ethical and legal issues; 4) health-care delivery systems and principles of public health; and 5) teaching techniques and research methods.

The clinical training must provide students hands-on experience working with individuals and families affected with a broad range of genetic disorders. These supervised experiences must expose students to the natural history, management and psychosocial issues associated with common genetic conditions and birth defects. Students must have opportunities to develop their genetic counseling skills in a variety of clinical genetics settings.

Currently, the eligibility criteria to sit for the ABGC certification exam include:

- Graduation from an accredited genetic counseling graduate program
- Fifty logbook cases acquired at approved sites - cases must represent a wide variety of counseling roles and clinical situations and be supervised by ABMG- or ABGC-certified individuals. The applicants' role in each case must be clearly documented.
- Letter of reference from a program director and two board-certified genetics professional

The general genetics examination used by both ABMG and ABGC is developed by ABMG, with ABGC contributing 10 percent of the questions. ABGC develops the specialty exam for genetic counseling and ABMG develops specialty examinations for MD and PhD trained individuals. The National Board of Medical Examiners (NBME) is involved in the development and administration of the examinations for both boards. To date, 1,675 additional genetic counselors have been certified by ABGC since 1993. Historically, the percentile scores on the general genetics examination for MD clinical geneticists and Master's level genetic counselors have not differed significantly, which further demonstrates genetic counselors' broad training in all areas of medical genetics.

To assure that knowledge and skills are maintained, beginning in 1996, genetic counselors certified by ABGC are required to go through a recertification process every ten years. Recertification can be obtained by re-examination or continuing education (25 hours/year).

While ABGC provides for credentialing for the genetic counseling profession, NSGC is the national professional organization for genetic counselors. NSGC is the leading voice, authority and advocate for the genetic counseling profession. NSGC has approximately 2,100 genetic counselor members, of whom 85 percent are certified by ABGC. In addition to providing many continuing education opportunities, NSGC has a code of ethics, produces position statements and practice guidelines, and is currently in the process of refining the definition of genetic counseling and a scope of practice for Master's level genetic counselors. **(ONS notes the importance of distinguishing between genetic counseling – which is a service provided by a number of health professionals –**

from genetic counseling used to describe particular practices of genetic counselors. The use of "the profession of genetic counselors" could help make the distinction.)

Credentialing for Genetics Nursing Practice. ISONG is an international nursing specialty organization that fosters the scientific and professional growth of nurses in human genetics. Incorporated in 1988, ISONG provides education and support for nurses providing genetics healthcare. ISONG promotes the integration of the nursing process into the delivery of genetic services and encourages the incorporation of the principles of human genetic principles into all levels of nursing education. As a professional society, they establish and maintain standards of practice for nurses in human genetics and support advances in nursing research in human genetics.

ISONG has taken the lead in working with nursing leaders to promote genetic nursing practice and develop a credentialing process for genetic nurses. In 1997, genetics nursing was recognized by the American Nurses Association as an official specialty of nursing practice. In 1998, ISONG established the Scope and Standards of Genetics Nursing Practice for genetic nursing to assure minimal levels of competency; these are currently being revised, with publication expected in 2005.

In 2001, ISONG approved formation of the Genetic Nursing Credentialing Commission (GNCC), which provides recognition for clinical nursing practice in healthcare with a genetics component. Beginning in 2001, nurses who are prepared with the Master's in nursing may qualify for the APNG credential. APNG credentialing is based on submitting a portfolio of accomplishments documenting the nurse's genetic expertise. This includes:

- Registered Nurse (RN) with at least a Master's degree in nursing or the equivalent
- At least three years of experience as a genetic nurse with a 50 percent genetic practice component
- Documentation of 50 cases where the APN has provided health care services with a genetic component in the past five years.
- Minimum of 50 contact hours of genetic content (e.g., acquisition of genetics content through classes, workshops or continuing education) in the past five years
- Demonstration of clinical competency by submitting four in-depth genetic case histories that show the nurse's ability to apply genetic knowledge according to the scope and standards of genetic nursing practice
- Submission of portfolio (including all of the above) that demonstrates the nurse's accomplishments and competency
- Three professional letters of reference

In 2002, GNCC was incorporated, and those prepared with a Bachelor's degree in nursing may qualify for the GCN credential (first offered in 2002). The GCN credential also is by portfolio and for non-Master's prepared nurses.

Other nursing subspecialty organizations such as Oncology Nursing Society (ONS) and the Association of Women's Health Obstetrical and Neonatal Nurses (AWHONN) have

established standards of practice and position statements, educational resources, and minimal practice requirements specific to their field for nurses practicing in genetics. The standards are consistent with the ISONG Standards of Practice but incorporate specialty-specific practice requirements. In addition, according to the National Coalition for Health Professional Education in Genetics (NCHPEG), there are 11 certified nursing specialties that incorporate genetics into their credentialing exam or core competencies. Lastly, there are 11 graduate or graduate certificate programs that focus on genetics as well as 16 short courses and web-based programs.[75]

ONS notes that many of its members – advanced practice nurses (NPs and CNSs) – are qualified to provide genetic counseling and should be able to receive reimbursement for the provision of such services.

Licensure of non-physician genetic service providers. All health care providers – physicians, nurses, genetic counselors, mental health professionals, social workers and other allied health professionals - assess risks, educate and inform patients. What distinguishes genetic counseling from education and counseling in other arenas is the combination of distinct and specific knowledge about genetics, inheritance, and human behavior (e.g., decision-making styles, coping mechanisms) combined with a focus on promoting autonomous decision-making through comprehensive informed consent. Therefore, the ability to provide genetic counseling requires a knowledge base and skill set that is distinct. The family's ability to make informed decisions about genetic testing, medical management and lifestyle depends on the qualifications and competence of the health professional **(e.g. physician, nurse, social worker, genetic counselor)** providing genetic counseling services.

ONS notes that physicians, nurses, and other health professionals not only assess risks, educate and inform patients but also are involved in helping individuals and families make decisions about lifestyle issues and medical management. This point should be made explicitly.

As genetic healthcare moves into mainstream medicine, primary care providers and non-genetic specialists will be required to provide increasing genetic care. Several recent studies document that few primary care providers feel knowledgeable about genetics and genomics, and in many cases they are not comfortable providing many of the components of genetic counseling.[77,78] A number of additional peer-reviewed articles demonstrate the lack of adequate training of healthcare providers in genetic counseling.[79] Additionally, two court cases - Pate v. Threlkel (Florida) and Safer v. Peck (New Jersey) - address the consequences that can occur when health providers fail to recognize the familial nature of genetic conditions and the concomitant duty to warn relatives at risk. When one considers this in combination with the relatively small number of physician genetic specialists (approximately 1,100 nationally), it seems likely that current and future genetic healthcare will require that services be provided by non-

[75] ISONG. 2005 Genetics and Health Workforce Survey Report.
[77] Pichert G, et al. Swiss primary care physicians' knowledge, attitudes and perception towards genetic testing for hereditary breast cancer. *Fam Cancer* 2003. 2(3-4):153-8.
[78] Kussman J, et al. Current and desired roles in the provision of genetic services among Family Physicians in the United States. *Journal of Genetic Counseling* 2004. 13(6):543-4.
[79] Giardiello FM, et al. The use and interpretation of commercial APC gene testing for familial adenomatous polyposis. NEJM 1997. 336(12):823-7. Other examples are listed in the bibliography at end of Appendix B.

physician genetic specialists, including nurses and genetic counselors with expertise in these areas. As such, ensuring the competence of our genetic workforce will be critically important.

Genetic counselor licensure, which is conducted on a state-by-state basis, **creates specified standards for all masters prepared genetic counselors providing genetic counseling services in that state.** Genetic counselor licensure enables employers and the public in the state to know that practicing genetic counselors have achieved a minimal standard, similar to licensure of physicians, nurses and social workers. Additionally, most licensed health providers are required to maintain their continuing education units regardless of certification status. As a result of licensure, title protection may prohibit unqualified practitioners from being able to represent themselves as genetic counselors. If a consumer of genetic counseling services wishes to lodge a complaint, the Department of Health and the Department of Medical Quality Assurance (or Department of Professional Licensure or other authority in the state) will not record complaints unless licensure of the profession exists.

ONS notes that these are important scope of practice and title restriction issues. Other licensure legislation (e.g. nurse practice acts) do not propose to regulate all other health professions providing any service within the scope of practice of that act. Nurses regulate nurses, physicians regulate physicians – although there is overlap in their scope of practice. ONS has concerns about genetic counselor legislation applying to all health professionals providing any service defined as falling within the scope of practice of genetic counselors, even if that person is licensed under her/his own professional practice act to provide that particular service. Given the broad definition of genetic counseling previously stated, this would have wide implications for every health professional providing any service included within the definition of genetic counseling. As such, ONS recommends the above edit to the definition of genetic counselor licensure.

ONS notes that there are many situations in which oncology nurses provide genetic information and counseling with regard to patients genetic results (e.g. HER-2/new, testing of leukemics for cytogenetic markers, etc.). It will be impossible for all genetic information to be given only by "qualified credential professionals." Genetic information is integrated into every aspect of nursing/medicine and as new advances are made this will become more so and not less. However, efforts should be made to license genetic counselors so they can bill for services and to make payment for such services more in line with the effort expended.

Nurses and MD geneticists working in genetics are already required to obtain state-based licensure in all states. Master's and PhD trained genetic counselors do not yet have licensure in most states. Utah is the only state that has currently enacted licensure of genetic counselors.[80] California and Illinois have passed legislation, but not yet

[80] Utah Administrative Code. Genetic Counselors Licensing Act Rules. www.rules.utah.gov/publicat/code/r156/r156-75.htm.

medical centers, and there is a slight decrease in overall health center employment (from 86 percent in 2000 and 2002).

According to data from NSGC, members see approximately 1.2 million clinical cases per year, and caseloads have been increasing approximately 5 percent per year since 2000. There has been a slight change such that the percent of genetic counselors reporting clinical care as a primary role is decreasing (from 86 percent in 2002 to 83 percent in 2004) while research as a primary role is increasing (from 30 percent to 32 percent).[109] Many ISONG members have also moved away from providing patient care, as indicated by the percentage of time they spend in individual patient care. Sixty-two percent of ISONG members spend 20 percent of their time or less directly involved with patient care.[110] Results from the ISONG nursing survey show that 68 percent of genetic nurses spend some portion of their professional time each week participating in research.[111] Twenty-two percent were involved in research for 10 percent of their time or less, while 46 percent were involved for 10 percent or more.[112] Data from the survey indicated that genetic nurses are generally comfortable with the level of support they receive from their institutions. Fifty-three percent are satisfied with institutional assistance (financial, human resources, etc.) and 16 percent are very satisfied.[113] Regarding reimbursement, ISONG members deem the adequacy of reimbursement for genetic services to be poor/fair (69 percent and 70 percent, respectively).[114]

ONS members note that many ISONG nurses are PhD prepared and working in research while those credentialed in genetics by GNCC are all in clinical practice or else they would not be eligible for the credential. ONS has concerns that the wording in this section suggests that ISONG nurses have moved away from patient care but NSGC members have not. Genetics roles for both genetics nurses and genetic counselors are changing and the two professional surveys cited are very different. ONS notes that many genetic counselors are now moving out of genetic counseling roles into non-clinical roles which may not include providing genetic counseling services. ONS suggests that the report include more of the data from the NSGC survey regarding trends for genetic counselors moving into non-clinical professional roles.

While the cause for this change in role diversification is not clear, it may be related to the increasing need to find salary support for those providing genetic counseling services, given the inability to generate significant billable service reimbursement. Additionally, if individuals providing genetic counseling services are required to spend increasing time on research or other administrative or teaching obligations in order to provide funding towards their salaries, the time available to provide clinical services will decrease,

[109] NSGC. Professional Status Surveys. http://www.nsgc.org/careers/pss_index.asp.
[110] Genetics Health Services Research Center, University of Maryland School of Medicine. Advanced Practice Nurses in Genetics: A Survey of ISONG Members.
[111] Ibid.
[112] Ibid.
[113] Ibid.
[114] Ibid.

concerns, particularly around the impact on workforce and subsequent access to genetic counseling services, at the committee's request.

Summary and Recommendations

SACGHS is in the position to make recommendations to the Department of Health and Human Services regarding the future of genetic services in health care. With the extraordinary impact of genetic information on health and society, genetic service providers are in the position to provide information and healthcare services to the public. Currently, the structure exists to guide training programs to produce quality, certified genetics professionals and licensure is being explored by a majority of states. However, without adequate reimbursement for genetic services, public health could be compromised by the provision of genetic services by uninformed healthcare providers without specialized training.

As our literature review has shown, genetic counseling has demonstrated value and is effective. Furthermore, providing coverage and reimbursement to non-physician genetic counseling service providers will decrease costs and likely increase access. No studies currently exist on the potential harms if non-physician genetic service providers are unable to obtain coverage and reimbursement for services. We strongly encourage the SACGHS to make formal recommendations to:

- Recognize, through licensure and other mechanisms, non-physician providers with expertise in genetics, as demonstrated by being credentialed by a national genetics organization appropriate for providers of genetic counseling services
- Advocate in all manners possible for the development of CPT codes that are specific to genetic counseling services for use by any qualified **provider and are reflective of the time spent in counseling**
- Support the funding of further studies to assess the value and effectiveness of genetic counseling services provided by non-physicians

In conclusion, data is presented here that outlines the qualifications, value and effectiveness of genetic counselors, credentialed genetics nurses and similarly trained healthcare professionals. SACGHS can now provide recommendations at high levels that will assist with achieving reimbursement for non-physician providers to allow quality, effective healthcare services. With reimbursement, these providers can become even more valuable in the financial realm of US health care and allow more medical facilities to offer quality genetic services to the public.

Comments of the Personalized Medicine Coalition to the

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

Draft Report

"Coverage and Reimbursement of Genetic Tests and Services"

May 5, 2005

The Personalized Medicine Coalition (PMC) is pleased to submit comments on the draft report of the Secretary's Advisory Committee on Genetics, Health, and Society entitled "Coverage and Reimbursement of Genetic Tests and Services." The PMC encompasses a broad spectrum of academic, industrial, patient and healthcare provider constituencies. Its expanding membership includes universities and academic medical centers, non-profit research entities, trade associations, patient advocacy groups, government officials (ex-officio), healthcare organizations, healthcare providers, payers, information technology companies and research-based commercial corporations that offer an array of products and services, including research tools, diagnostic technologies and products, screening services and therapeutic interventions. The PMC is a non-governmental, non-profit group, dedicated to advancing the understanding and adoption of personalized medicine concepts and products for the ultimate benefit of patients who need them.

We define personalized medicine as the use of new methods of molecular analysis to better manage a patient's disease or predisposition towards a disease. It aims to achieve optimal medical outcomes by helping physicians and patients choose the disease management approaches likely to work best in the context of a patient's genetic and environmental profile. The PMC seeks to promote discussion and understanding that will lead to the development of sound public policy on matters that will affect the realization of the promise of personalized medicine.

Founded to advance genomic medicine, the PMC has a keen interest in the current state of coverage and reimbursement of genetic/genomic tests and services as well as any and all efforts to improve patient access through a revamped test evaluation and reimbursement process. **We encourage the Committee to focus on potential private sector solutions when it assesses historically inadequate methodology for establishing appropriate reimbursement for genetic/genomic services. In particular, it should encourage the development of sophisticated new tests and services by recommending the establishment of adequate reimbursement policies.**

The PMC requests the opportunity to participate in the Committee's development of appropriate coverage and reimbursement recommendations for genetic/genomic services. We look forward to working with the Committee as it considers the broad range of patient and societal issues raised by the development and use of genetic/genomic services leading to a personalized medicine paradigm.

Edward Abrahams, PhD
Executive Director
Personalized Medicine Coalition
1401 H Street, NW, Suite 650
Washington, DC 20005