prevailing costs, which exist currently; *Frequency:* Annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 11,300; *Total Annual Responses:* 11,300; *Total Annual Hours:* 6385.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 23, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–2277 Filed 1–29–97; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Program Announcement for a Cooperative Agreement To Initiate an Interdisciplinary Center for Community-Based Learning

The Health Resources and Services Administration (HRSA) announces the awarding of a sole source cooperative agreement to the Association of Academic Health Centers to plan for and implement an Interdisciplinary Center for Community-Based Learning. This activity will be supported under the authority of Title III, Section 301, of the Public Health Service Act. A proposed three-year period of support beginning in fiscal year 1997 is anticipated with approximately $100,000 per year.

The project will (1) strengthen and institutionalize the academic health centers commitment to interdisciplinary community-based learning, particularly in under served community settings, (2) provide expertise to academic health centers in regard to model interdisciplinary community-based curricula and training sites, and (3) support an interdisciplinary network of health care professionals working to create and strengthen an interdisciplinary community-based curriculum.

The Association of Academic Health Centers was chosen because it is the recognized professional association representing academic health centers, with a mission that ''seeks to explore and study issues that relate to greater coordination of health-related schools and programs, both within and among institutions, interdisciplinary and multiprofessional concerns.''

It also has previously established relationships with several multiprofessional groups and associations which are actively developing an agenda for interdisciplinary community-based learning and have ready access to information regarding all interdisciplinary community-based training programs at academic health centers in the country.

Federal Involvement

The Cooperative Agreement mechanism is being used for this project to allow for substantial Federal programmatic involvement with the planning, development, administration, and evaluation of the Interdisciplinary Center for Community-Based Learning.

Requests for Additional Information

Requests for additional information regarding this sole source cooperative agreement should be directed to: Sue Hassmiller, Ph.D., R.N., Bureau of Health Professions, Room 8–05, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301)443–6700, Fax: (301)443–2111, Email: shassmiller@hrsa.dhhs.gov

Dated: January 23, 1997.

Ciro V. Sumaya,

Administrator.

[FR Doc. 97–2292 Filed 1–29–97; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

Proposed Recommendations of the Task Force on Genetic Testing; Notice of Meeting and Request for Comment

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Task Force on Genetic Testing was created by the National Institutes of Health (NIH)-Department of Energy (DOE) Working Group on Ethical, Legal, and Social Implications of Human Genome Research to make recommendations to ensure the development of safe and effective genetic tests, their delivery in laboratories of assured quality, and their appropriate use by health care providers and consumers. The Task Force reviewed genetic testing in the United States, promulgated interim principles consonant with its goals (''Interim Principles'', available at http://ww2.med.jhu.edu/tfgtelsi), and has taken public comments into consideration in revising them. Over the past eight months the Task Force has discussed policies to implement several of its principles. It now submits proposed recommendations for public comment. These proposed recommendations are available at http://ww2.med.jhu.edu/tfgtelsi.

DATES: To assure consideration by the Task Force, comments must be received on or before March 10. The Task Force will meet on March 17 from 8:00 a.m. to recess and on March 18 from 8:00 a.m. to adjournment at approximately 12:00 noon. The meeting will take place at the Doubletree Inn at the Colonnade, 4 West University Parkway, Baltimore, Maryland, (410) 235–5400. Time permitting, guests will have the opportunity to speak on comments already submitted, but no formal time is being set aside. A final report, including the principles and recommendations, together with background information and comments, will be issued shortly after the meeting.

ADDRESSES: Written comments should be sent to Neil A. Holtzman, M.D.,M.P.H., Genetics and Public Policy Studies, The Johns Hopkins Medical Institutions, 550 N. Broadway, Suite 511, Baltimore MD, 21205–2004, faxed to Dr. Holtzman at 410–955–0241, or e-mailed to tfgt-a@welchlink.welch.jhu.edu. Individuals who plan to attend the March 17–18 meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Holtzman in advance of the meeting.

Background

Scientific breakthroughs have greatly accelerated the discovery of genes which, when altered by mutation, result in disease or in increased risk of disease. When these mutations occur in the germline (sperm or egg), they can be passed from one generation to the next. These basic research discoveries lead readily to the development of tests for inherited mutations. The number of DNA-based genetic tests and the volume of testing are increasing steadily. This has been accomplished in part by the work of the new biotechnology industry.

Aware of the potential for harm as well as benefits, the National Center for Human Genome Research (NCHGR/NIH) set aside from its inception a portion of its appropriation for consideration of ethical, legal, and social implications of human genome research. As part of its joint program with NCHGR, the Department of Energy (DOE) also set aside a portion of its appropriation. This initiative to anticipate problems in order to maximize benefits and prevent or minimize harm, of which the Task Force on Genetic Testing is one activity, is unprecedented in the development and application of new biomedical technologies. The principles and recommendations of the Task Force represent an attempt to build on successes and prevent problems of the past and present from continuing in the future. Some past and present problems will be described in the final report of the Task Force.

For the most part, genetic testing in the United States has developed successfully, providing more options for avoiding, preventing, and treating inherited disorders. This success is largely the result of testing being undertaken in genetic centers or in consultation with geneticists and genetic counselors. In the next few years, the use of genetic testing is likely to expand rapidly while the number of genetic specialists will remain essentially unchanged. This means that a greater burden for making genetic testing decisions will fall on providers who have had little formal training or experience in genetics. The problems they will encounter in providing genetic tests are seldom encountered in other areas of medicine.

- Much of medical practice and medical testing is provided for people who are already ill. Genetic testing will increasingly be used to predict risks of future disease in healthy people. Telling healthy people about future risks can heighten uncertainty and cause psychological distress.
- For many other disorders, interventions are available to cure, prevent or ameliorate the condition. This is not the situation for many disorders for which genetic testing is possible. Positive results of some tests confront patients with difficult reproductive decisions. These are personal decisions that should not be unduly influenced by providers or society.
- Few other tests provide information on the risk of future disease to healthy relatives of the person being tested. Providers have little guidance in communicating genetic risks to relatives and, simultaneously, keeping results confidential.
- Differences in the frequency of disease-related mutations among ethnic groups can influence the appropriateness of providing some genetic tests, and heighten concern about discrimination and stigmatization.

In addition, the predictions made by genetic tests are not always certain and often no independent test is available to confirm the prediction. Test uncertainty is not unique to genetic tests. However, the psychological and physical effects of testing are often greater for imperfect genetic tests when no treatment is available or when interventions of unproven efficacy are life-long or irreversible.

Key Principles

The Task Force enumerated principles to address many of the problems raised by predictive genetic tests. Its proposed recommendations are an effort to implement several of these principles, highlighted below:

Validity and Utility of Genetic Tests

- Before a genetic test can be generally accepted in clinical practice, data must be collected to demonstrate the benefits and risks that accrue from both positive and negative results. The primary responsibility for data collection falls on test developers. For many tests, however, data collection must continue after tests are introduced into practice.
- Protocols for the clinical validation of genetic tests must receive the approval of an institutional review board (IRB). At present, IRBs have the principal responsibility for the protection of subjects participating in validation studies. The Task Force is concerned that current limitations of IRBs might impair review of genetic testing protocols.

Laboratory Quality and Certification

- A national accreditation program for laboratories performing genetic tests, which includes on-site inspection and proficiency testing, is needed to promote standardization across the country. Although most laboratories providing clinical laboratory tests are certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, current regulations do not adequately ensure the quality of genetic testing. Professional organizations have developed more appropriate quality assessment of genetic tests than is required under CLIA, but laboratories performing genetic tests are not required to use these voluntary accreditation mechanisms.

Professional Competence in Genetics

- Health care professionals involved in the provision of genetic tests should be well-informed about their implications, benefits and risks. Students preparing for careers in health care and current health care providers themselves are not being taught enough about human genetics and genetic testing. Consequently, not all providers in practice today may have adequate competence to offer and interpret genetic tests. Related problems are the lack of standards for formal assessment of new genetic testing technologies and the limited impact of current efforts to establish clinical guidelines for when and how genetic tests should be offered.

Rare Genetic Diseases

- The development and maintenance of tests for rare genetic diseases must be encouraged. At a time when genetic tests for common complex disorders are increasing, tests for rare disorders may be developed at a slower rate than in the past. Some that have been available may be more difficult or impossible to obtain. Many physicians do not have access to the best available information and resources to identify and manage rare diseases, or know where to turn for help.

Informed Consent and Confidentiality

- Informed consent for a validation study must be obtained whenever the specimen can be linked to the subject from whom it came. When specimen identifiers are retained in either coded or uncoded form, the opportunity exists of being able to contact subjects even if the intent of the original protocol is not to do so.
- Health care providers must describe the features of the genetic test, including potential consequences, to potential test recipients prior to the initiation of predictive testing in clinical practice. Individuals considering genetic testing should be told the purposes of the test, the chance it will give a correct prediction, the implications of test results and the options, and the benefits and risks of the process. The responsibility for providing information to the individual lies with the referring provider, not with the laboratory performing the test.
- It is unacceptable to coerce or intimidate individuals or families regarding their decision about genetic testing. Respect for personal autonomy is paramount. People being offered testing must understand that testing is voluntary. Whatever decision they make, their care should not be jeopardized. Information on risks and

benefits must be presented fully and objectively. A non-directive approach is of the utmost importance when reproductive decisions are a consequence of testing or when the safety and effectiveness of interventions following a positive test result have not been established. Obtaining written informed consent helps to assure that the person agrees to testing voluntarily.

- Results should be released only to those individuals to whom the test recipient has consented or subsequently requested in writing. Means of transmitting information should be chosen to minimize the likelihood that results will become available to unauthorized persons or organizations. Under no circumstances should results be provided to any outside parties, including employers, insurers, government agencies, without the test recipient's written consent. Unless potential test recipients can be assured that the results will not fall into unauthorized hands, some will refuse testing for fear of losing insurance or employment.
- Health care providers have an obligation to the person being tested not to inform other family members without the permission of the person tested except in extreme circumstances. Disclosure by providers to other family members is appropriate only when the person tested refuses to communicate information despite reasonable attempts to persuade him or her to do so, and when failure to give that information has a high probability of resulting in irreversible or fatal harm to the relative. When test results have serious implications for relatives, it is incumbent on providers to explain to people who are tested why they should communicate the information to their relatives.

Recommendations

A Genetics Advisory Committee

The Task Force joins the NIH–DOE Joint Committee to Evaluate Ethical, Legal, and Social Implications Program of the Human Genome Project in recommending that the Secretary of Health and Human Services (HHS) create, in the Office of the Secretary, a federally chartered Advisory Committee on Genetics and Public Policy (hereafter the Advisory Committee) whose members should include the stakeholders in genetic testing. The Secretary should establish formal liaison between the Advisory Committee and an already-established HHS interagency group considering policies of the Department relevant to the development and provision of genetic tests. In addition to assisting the Advisory Committee, this interagency group should develop coordinated and consistent genetic testing policies in the Department. The two committees whose creation is recommended later in this document, one to advise the Food and Drug Administration (FDA) on assuring the validity and utility of new genetic tests, the other to advise the Clinical Laboratory Improvement Advisory Committee on assuring the quality of laboratories performing genetic tests, should report to the Advisory Committee through the interagency group.

Need for Interim Action

The Task Force recognizes that the formation of the Advisory Committee could take some time. It is also aware that organizations have on occasion developed and offered genetic tests without always collecting data on test validity and utility and without external review. Consequently, the public is not being adequately protected.

The Task Force recommends that the Secretary of HHS use existing agencies and policies to ensure that the public will have adequate protection from predictive genetic tests that have not been adequately validated and whose clinical utility has not been established. It suggests two possibilities:

(1) FDA uses its acknowledged authority under the Medical Device Amendments of 1976 (21 USC 321–392) to the Food, Drug, and Cosmetic Act (21 USC 301–392), to ensure that *all* organizations developing new, predictive genetic tests submit protocols to an institutional review board (IRB).

(2) The Health Care Financing Administration (HCFA) establish policies under Medicare and Medicaid to reimburse for certain genetic tests (see below) only when they are performed in laboratories that can provide evidence that (a) the test has been clinically validated (based on published information or information provided by the test developer) or that it is participating in a systematic validation plan, and (b) they are qualified to provide such tests (see below, Laboratory Quality). Once HCFA adopts such policies it is likely that other third-party payers will quickly follow.

The Task Force makes a similar recommendation to the Department of Defense for reimbursement under the Civilian Health and Medical Program Uniform Services (CHAMPUS).

The need for stringent scrutiny of certain predictive genetic tests. The Task Force has sought to find ways to identify tests that are more likely to pose significant risks in their developmental stage and when they enter clinical practice. It recognizes that existing resources for scrutinizing tests are limited. Consequently, the Task Force has attempted to identify characteristics of tests and diseases that raise the greatest concern and can be used to prioritize tests for stringent scrutiny. These characteristics include, but are not necessarily limited to:

- *A test's potential for predicting serious future disease in healthy people (or their offspring).* Even if a test developer's intended use of the test may not be for predictive purposes, the potential for such use, as is the case for DNA-based genetic tests, increases the level of scrutiny needed. The absence of a confirmatory test heightens the scrutiny a test needs.
- *Test uncertainty.* When *only* healthy people with positive test results will develop the disease and when all people with positive results will develop it, less scrutiny is needed than when these conditions are not fulfilled.
- *The safety and effectiveness of clinical interventions in those with positive test results of predictive tests.* Unless the safety and effectiveness of clinical interventions for those with positive test results have been established, people who test positive cannot be confident that interventions will prevent the disease or improve its outcome if it does occur.

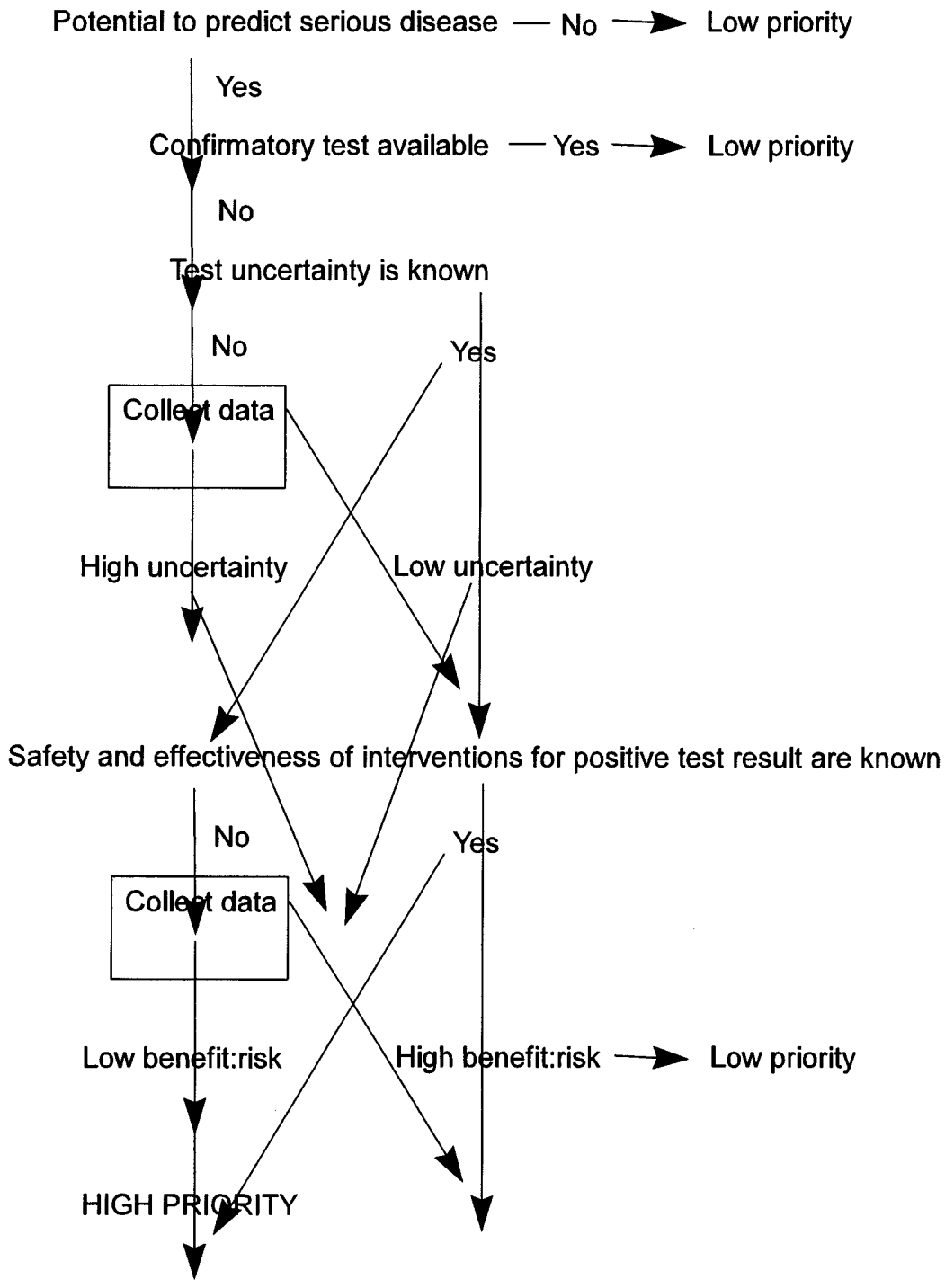
Other characteristics that might play a role in prioritizing are: the frequency of occurrence of the disorder(s) detected by the test under review, the use of the test for population screening, whether the disorder(s) detected occur more frequently in some ethnic groups than others, and whether the reliability of the test under routine clinical laboratory conditions has been established.

There are several junctures at which these characteristics should be applied to specific tests. The first occurs in the review of protocols for investigating the validity and utility of new tests. Subjects participating in trials or pilot programs to establish validity and utility must be adequately protected, particularly when they will be notified of the results or simply when personal identifiers will be retained with the specimens. The protocol must have sufficient scientific merit to justify the participation of subjects. The characteristics provided above could be used by IRBs as a checklist to make sure that the protocol addresses important issues in test development. For instance, if applicants fail to present data on test uncertainty, they should be required to supply that information or, if it is unavailable, to collect the requisite data. A grading system could be devised so that protocols exceeding a certain score would be designated as requiring ''stringent scrutiny.'' Alternatively, the characteristics can be layered in an

algorithm or decision tree. (See Figure) For instance, if a test has the potential to predict future disease and there is no confirmatory test, the next step in deciding whether it needed stringent scrutiny would be the extent of test uncertainty. If this was unknown, data collection would be needed. Once data were collected, the next question is the safety and effectiveness of interventions in those with positive results. If the benefit:risk ratio of intervention is high and test uncertainty is low, the test would not require close scrutiny. Even if test uncertainty is low, close scrutiny would be needed if the safety and effectiveness of interventions had not been established.

BILLING CODE 4140–01–P

Algorithm for Prioritizing the Scrutiny of Genetic Tests



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The second juncture occurs when a test developer believes the test is appropriate for clinical use. Review by an organization independent of the developer is needed to ensure that the public will benefit from the test. The Task Force is concerned that the number of tests might overwhelm external review processes and needlessly delay the availability of tests of potential benefit. To reduce the likelihood of backlogs, the criteria should be used to set priorities for stringent scrutiny. Tests of low priority would enter clinical practice without scrutiny but could be considered again at the third juncture.

The third juncture occurs when the test is clinically available and there are concerns that (1) it will not be used when it is indicated, (2) it will be used for inappropriate indication(s), or (3) that more data on validity and utility are needed. The same set of criteria can be used to set priorities for post-marketing surveillance requirements and establishing guidelines for test use.

The Task Force recognizes that as information and experience is gained, the scrutiny a test needs is likely to diminish. As further scientific and technical advances occur, other criteria may become more important and other types of tests may then need stringent scrutiny.

Assuring the Validity and Utility of New Genetic Tests

The Task Force is concerned that the high workload of IRBs, their variability in community representation, in evaluating protocols, and in expertise germane to the review of genetic tests, as well as the conflicts of interest that can arise in local review, impairs current review of genetic tests that warrant stringent scrutiny. The Task Force urges the Office of Protection of Human Subjects from Research Risks, with input from the proposed Advisory Committee, to address these problems. The Task Force is also concerned that organizations that do not use federal funds for the research and development of genetic tests that will be marketed as services may not seek outside review from an independent IRB. The Task Force is also concerned that data needed after tests enter clinical practice may not be collected.

The Task Force urges the proposed Advisory Committee to recommend to the Secretary the creation of a National Genetics Board (NGB) whose goal would be to assure the protection of human subjects in the development of genetic tests with the potential to predict future disease. NGB members should be broadly representative of stakeholders in genetic testing, including but not limited to test developers (manufacturers and clinical laboratories), consumers, professional societies, health care providers, and insurers. Some of its members must be scientists capable of reviewing scientific protocols. The Board should have its own staff.

NGB would develop a checklist that would enable local IRBs to identify protocols that meet criteria for stringent scrutiny. NGB would function along the lines of one of the following models, each of which each has advantages and disadvantages. The Task Force did not reach consensus on which model NGB should follow. The Task Force is especially interested in public comments on the alternatives.

(1) NGB reviews all protocols requiring stringent scrutiny. This assures that expert assessment with broad input will be consistently obtained and conflicts of interest will be minimized. However, if local IRBs also review protocols before or after they are sent to the NGB, funding or activation of the protocols could be delayed. NGB approval would be required before federal funds are awarded. NGB should also be available to review protocols from commercial organizations developing genetic tests without federal funds.

(2) NGB has the discretion to choose which protocols among those in need of stringent scrutiny it will review. Those protocols which NGB elects not to review will be sent back to the local IRB for review. Based on its selective review, NGB will issue advisories to local IRBs to assist them in the review of similar protocols. Under this model, the advantages of the first model are reduced, but so is NGB's work load; local IRBs retain greater authority. Delays are likely as protocols move between local IRBs and NGB.

Under both model (1) and (2), local IRBs could also request NGB review of other genetic testing protocols. Based on its available resources and backlog, NGB could decide whether or not to review these protocols. NGB could also assume responsibility for the primary review for the protection of human subjects of multi-center and other collaborative studies for the validation of genetic tests.

(3) NGB focuses on generic policy issues and sets general guidelines for review. It is available for consultation and advice, but has no mandatory review function. Protocols that a local IRB believes raises novel and problematic issues could be sent to NGB for analysis and comment. The advantages and disadvantages of this approach are similar to those described for the second model; the likelihood of consistent review is further reduced, but as review is entirely the responsibility of the local IRBs, delays are less likely.

Role of FDA. The Task Force recognizes that developers of genetic tests who do not rely on federal funds are under no legal obligation to submit protocols to the proposed NGB and have not always obtained IRB approval for validation protocols of tests they plan to market as laboratory services. If tests requiring stringent scrutiny were regulated by FDA, even if they were to be marketed as services, then under existing regulations (21 CFR part 56), protocols for clinical validation would have to be submitted to an IRB regardless of whether they came from federally-funded organizations or not. Although the FDA acknowledges its authority under the Medical Device Amendments to regulate genetic tests marketed as services, it has chosen not to do so. (Under the CLIA, clinical laboratories must demonstrate analytical validity of their tests but there is no statutory or regulatory requirement for them to establish the clinical validity or utility of clinical laboratory tests.)

The Task Force recommends that FDA:

(1) Establish a Genetics Advisory Panel under the Medical Devices Amendments (21 USC 321–392) which would advise FDA on: (a) Strategies for prioritizing genetic tests; (b) the scientific, ethical, and social merits of applications FDA receives for marketing genetic tests; and (c) other matters germane to genetic testing. In carrying out its first function, this panel could consult with the proposed NGB if it is established, but it should not delay formulating its strategies until that time.

(2) Adopt a strategy to prioritize predictive genetic tests according to the degree of scrutiny they need.

(3) Publicize the requirements it develops for tests requiring stringent scrutiny.

(4) Require that new genetic tests meeting criteria for stringent scrutiny be regulated under the Medical Device Amendments (21 USC 321–392; 21 CFR parts 200 *et seq.*) regardless of whether their sponsor's intention is to market them as services or as kits.

Although a majority of the Task Force supported all of these recommendations, a consensus was not reached on the fourth. The Task Force is especially interested in public comments on this recommendation.

Data collection. The data needed to definitively establish the validity and utility of a genetic test may take so long to collect that if test developers could

not market their tests they would be deterred from developing them. Data collection is also a problem for rare genetic diseases for which data from several sources will have to be collected to establish the validity and utility of testing. Without a formal plan and procedure for prospective data collection, data will undoubtedly be lost and the time to reach definitive conclusions will be prolonged.

The Centers for Disease Control and Prevention (CDC), in cooperation with NCHGR, should expand the monitoring of genetic disorders in order to provide data on the validity of tests and post-test interventions. It should establish procedures for tracking healthy individuals with positive test results, as well as those diagnosed with inherited disorders, to learn more about (1) test validity, (2) the natural history of such disorders, and the (3) safety and effectiveness of interventions. The collection of this data should be undertaken in cooperation with local providers and consultants in genetics and other relevant specialties. At all times the confidentiality of the data collected must be protected.

For tests for which long periods of data collection are needed, FDA should grant conditional premarket clearance or approval before all necessary data are collected to make promising new technologies available to the public and enable test developers to obtain an adequate return on their investment in test development. Developers would be responsible for continuing to collect data as in the premarket phase and make it available to FDA. When sufficient data are collected, FDA will decide whether or not to grant unconditional approval. Conditional premarket approval should be granted to tests when FDA considers it likely that the test will prove to make an important contribution to the prevention or management of the disorder. Under this circumstance, third-party payers, including government programs such as Medicare, Medicaid, and CHAMPUS, should reimburse for the test once it has been conditionally approved. Managed care organizations should also cover tests given conditional approval.

Technology assessment. Many tests currently on the market have not been systematically validated nor subject to external review. New tests that go through these processes will be modified under clinical conditions.

Technology assessment is important to guide providers and consumers in the use of genetic tests, but is unlikely to be undertaken by existing technology assessment agencies because genetic tests do not entail huge expenditures of health care dollars. NGB should serve as a clearinghouse for technology assessments of genetic tests that are about to enter, or already are used in, clinical practice. It could secure and coordinate assessments of those technologies it considers in need of stringent scrutiny and coordinate assessments to avoid unnecessary duplication. NGB could also make recommendations on appropriate use of genetic tests with input from relevant professional societies as well as consumer groups.

Assuring Laboratory Quality

The Task Force is concerned about the lack of Federal law or regulation covering genetic tests except for cytogenetic tests, limitations of existing voluntary quality assurance and proficiency testing programs, inadequate assessment of the pre-and post-analytic phases of testing, and the absence of public information about laboratories satisfactorily performing genetic tests under existing voluntary assessments.

CLIA has no standards specific to genetic tests except for cytogenetics. Currently New York State requires certification of all laboratories performing clinical genetic tests on state residents. The College of American Pathologists/American College of Medical Genetics'' (CAP/ACMG) Molecular Pathology accreditation program is also designed to assess performance on the special problems of genetic tests, placing greater emphasis on the pre-and post-analytic phases of testing than other programs. However, CLIA-certified laboratories performing genetic tests are not required to be assessed by the CAP/ACMG program. If they are not, genetic tests could be accredited under CLIA without being specifically assessed. Furthermore, laboratories that participate in CAP/ACMG's Molecular Pathology program do so voluntarily and not under CAP's regulatory (''deemed'') authority under CLIA. (Under CLIA, HCFA has the authority to grant deemed status equivalence to an outside organization that has a quality assurance and proficiency testing survey program with standards equal to or greater than CLIA's. CAP's general proficiency testing program has been ''deemed'' equivalent by HCFA.) As CLIA has not established standards specifically for genetic tests, it has no authority to approve the CAP/ACMG Molecular Pathology program.

Differences between state law and Federal laws and regulations (and among different nations), create overlapping and often duplicative requirements for laboratories. The Task Force recommends that a national accreditation program of quality assurance and proficiency testing for genetic tests equivalent to or more stringent than those of New York State and CAP/ACMG, should be established under CLIA. This accreditation program should include proficiency testing and inspection of laboratories performing genetic tests. Quality assurance includes: (a) The skill and training of laboratory staff; (b) evidence of successful execution of the complex techniques involved in genetic testing to produce a correct and verifiable test result; and (c) assessment of pre-testing and post-analytic phases of testing.

Until such time as a national accreditation program is established under CLIA, the CAP/ACMG Molecular Pathology program, expanded to encompass all methods currently in use in genetic testing, might itself serve as the national program, and should be accessible to any laboratory providing clinical genetic testing. When a national program is established the CAP/ACMG Molecular Pathology program should have deemed status.

The Task Force recommends the establishment of a Genetics Advisory Committee to the Clinical Laboratory Improvement Advisory Committee (CLIAC) to help address the deficiencies of CLIA in assuring the quality of genetic tests. The work of this genetics committee should be reported to the Advisory Committee on Genetics and Public Policy through the interagency group previously discussed. The work of the proposed CLIAC advisory committee should also be coordinated with other HCFA programs, as well as FDA, CDC, and other Federal agencies involved setting genetic testing policies.

Pre-test education and post-test counseling components of clinical laboratory tests are critically important parts of the laboratory test to physicians who are not generally well informed about genetic tests. Preanalytic components include the information about the test that laboratories make available to providers and consumers and the informed consent documents and processes that laboratories may require. Postanalytic components include the information (interpretation) given with the test result and counseling services provided or arranged by laboratories. In any quality assurance program, closer scrutiny is needed of pre-and post-test analytic components of genetic testing than current assessment programs provide. The Task Force recommends that CAP/ACMG seek advice and input from consumer groups such as the Alliance of Genetic

Support Groups, as well as from the National Society of Genetic Counselors (NSGC), on standards for the quality of pre-and post-analytic components of genetic testing.

The Task Force recommends that CAP/ACMG periodically publish, and make available to the public, a list of laboratories performing genetic tests satisfactorily under its voluntary program. The Task Force recognizes that CAP is not currently required to publish, and has not published, the names of laboratories performing satisfactorily in the CAP/ACMG voluntary Molecular Pathology program. Until such time as a program is established under CLIA, publication will enable providers and consumers to select approved laboratories and will also serve as an incentive for laboratories to participate in the CAP/ACMG quality assessment program. This information should be disseminated using the Internet and other media accessible to consumers and providers.

Managed care organizations and other third-party payers should limit reimbursement for genetic tests to the laboratories on the published list of those satisfactorily performing genetic tests. Implementation of this recommendation will be especially important as more managed care organizations move to restrict access to laboratory services for their members to a single contracted laboratory (which may or may not be on the list of qualified laboratories).

The Task Force recommends that efforts should be made to harmonize international laboratory standards to assure the highest possible laboratory quality for genetic tests. At present, no mechanism exists to create international standards of laboratory quality and proficiency for genetic tests. Current United States regulations require any foreign laboratories performing clinical laboratory tests on U.S. residents to hold a CLIA certificate even if their nation's laboratory standards are more stringent that those of CLIA (e.g., as is the case with Canada).

Provider Competence

The Task Force wants to ensure that non-geneticist providers adequately appreciate many of the general issues that should be considered and discussed in offering, providing, and interpreting predictive genetic tests. These issues include: (1) Who should be offered a specific test; (2) the benefits and risks of each test; (3) the need for, and the content of informed consent, and how consent should be administered; (4) an explanation of test results; and (5) familiarity with genetic counseling strategies and principles. A provider's need for knowledge is particularly keen when tests are in transition from research to clinical use and when clinical utility is still under investigation and there are no established practice guidelines.

The Task Force endorses the recent establishment of a National Coalition for Health Professional Education in Genetics by the American Medical Association, the American Nurses Association, and the NCHGR. The Coalition should work in consultation with its member organizations, including non-genetics professional societies, to encourage the development of core curricula in genetics, with an emphasis on having individual professional organizations determine their own needs in the design and execution of the programs. It should also encourage input by consumers in the development of these curricula. The Coalition should serve as a registry of, and clearinghouse for, information about various curricula and educational programs, grants, and training pilot programs in genetics education. By providing educational resources, it should encourage professional societies to track the effectiveness of their respective educational programs. The Coalition should disseminate information on available programs in order to avoid inefficient duplication.

The Task Force strongly recommends that board examinations used for physician and specialty certification increase both the quality and the quantity of questions related to genetics. This should further stimulate the teaching of genetics to medical students, as well as residents in many specialties. The scores on these questions should serve as feedback to improve curricula.

Ultimately, implementation of these first two recommendations will improve the provision of care. The remaining recommendations are directed at short-term needs.

For those specialties which both require periodic passage of an examination for recertification and whose practitioners are likely to order predictive genetic tests, examinations for recertification should include questions on medical genetics and genetic testing, including predictive testing.

Hospitals and managed care organizations should use credentialing and other mechanisms (such as prior authorization) to limit the offering of certain predictive genetic tests to genetic health care professionals and physicians who have demonstrated their competence in dealing with the issues enumerated above. Successful completion of continuing education courses could be required to demonstrate competence. (The National Coalition for Health Professional Education in Genetics should be able to provide information on available programs for learning about the relevant issues.)

Predictive genetic tests requiring stringent scrutiny, as previously described, should be among those for which special credentials are needed. As professional experience is gained with tests for certain disorders, special credentialing may no longer be required, but other new genetic tests may take their place. Third-party payers could also establish policies that allow only properly credentialed providers to be reimbursed for their role in providing tests.

The Task Force is of the opinion that primary care providers and other non-geneticist specialists can and should be involved in genetic testing. However, they must first gain sufficient familiarity with the issues involved. In some cases, providers should work closely with genetic health care professionals who can serve as experienced repositories of in-depth information about many aspects of genetic testing. Several laboratories already require this collaboration. In this rapidly changing field, providers should maintain their knowledge of genetics throughout their professional lives.

Credentialing bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA) should assure that hospitals and other health care organizations develop continuous quality improvement programs focusing on genetic testing. Systematic and periodic medical record review, with feedback to providers, is one means of assuring appropriate use of genetic tests. Such review should assess the extent to which providers' records for frequently-ordered predictive genetic tests are in accord with per-determined criteria. These criteria should include, but not be limited to, appropriate indications for offering the test, offering the test when it is indicated, and documentation of: informed consent when appropriate, the test result, information given to the patient, and the patient's response. Mechanisms should be in place to assure that review procedures will not infringe on the confidentiality of the medical records.

Except when time is of the essence, such as with certain prenatal genetic tests, obtaining informed consent and actually performing the test should be

delayed several days after the test is offered and information given to the patient. This would give people considering testing the opportunity to absorb information about the test, contemplate the implications of testing, and discuss testing with others.

Rare Genetic Diseases

Physicians who encounter patients with symptoms and signs of rare genetic diseases should have access to the best available information about rare genetic diseases. This will enable them to include such diseases in their differential diagnosis, to know where to turn for assistance in clinical and laboratory diagnosis, and to find laboratories that test for rare diseases. The quality of laboratories providing tests for rare diseases must be assured, and a comprehensive system to collect data on rare diseases must be established. Although these are issues that relate primarily to the diagnosis of patients with symptoms and signs, they have major implications for predictive testing in asymptomatic relatives who may be at risk of disease or who are carriers of alleles for the disease and whose future children may be at risk.

The Task Force is aware of a number of efforts to address one or more of these issues, including the availability of disease-based databases on research projects by the NIH Office of Rare Diseases (ORD), on information for consumers and providers by the National Organization of Rare Disorders, the Alliance of Genetic Support Groups and its member organizations, and by the American Academy of Pediatrics, and on clinical laboratories providing tests through the Helix National Directory (available to providers only). In addition, the Society for Inherited Metabolic Disorders is compiling information for providers on diagnostic evaluations of rare disorders, and the ACMG is developing databases on tests that should be used for diagnosis of specific disorders.

The Task Force recommends that NIH give ORD a mandate to coordinate these public and private efforts to improve awareness of rare genetic diseases. Such coordination is important to avoid unnecessary duplication, to use expertise most efficiently and to address the concerns of the various groups. ORD could serve as a gateway for provider and public inquiries about these disorders.

In cooperation with other organizations, and on a regular basis, ORD should identify laboratories world-wide that perform tests for rare genetic diseases, the methodology employed, and whether the tests they provide are in the investigational stage, or are being used for clinical diagnosis and decision making. Laboratories should notify ORD about impending cessation of their testing so that provisions for a transition to other laboratories can be made.

ORD should also be responsible for assuring that tests for rare genetic diseases, which have been demonstrated to be safe and effective, continue to be available if and when their developers leave the field, and no other laboratory is prepared to offer the test, and/or the methodology is too complex to be readily adopted by other laboratories. The Task Force urges that additional funds be appropriated for ORD to undertake this expanded role.

In accordance with current law, the Task Force is of the opinion that any laboratory performing any genetic test on which clinical diagnostic and/or management decisions are made should be certified under CLIA. If specimens must be sent to a non-CLIA licensed research facility, the referring physician must be made aware of the investigative nature of the test.

The Task Force recognizes that the current CLIA certification process may place a heavy burden on some laboratories doing small numbers of diagnostic tests for rare diseases. Several laboratories currently performing these tests are primarily engaged in research, with the tests stemming from their research efforts. Without accommodation, some tests may cease to be available. Therefore, the Task Force recommends that the proposed Genetics Advisory Committee to CLIAC explore means to simplify compliance with CLIA without sacrificing quality, just as accommodations have been made for rare genetic disease testing within the New York State Department of Health laboratory permit process. Recognizing current deficiencies under CLIA in the assessment of genetic tests (discussed above), the Task Force also encourages CAP/ACMG to make its clinical accreditation programs available to low-volume laboratories that are unaffiliated with a hospital, and modify its procedures to accommodate such laboratories.

Directories of laboratories providing tests for rare diseases should indicate whether or not the laboratory is CLIA-certified and whether it has satisfied other quality assessments, such as the CAP/ACMG program.

The recommendation made earlier, calling on the CDC to expand its data monitoring capabilities, is intended to include rare diseases. Collecting data on rare diseases will require coordinating data from multiple sources. It is particularly needed to validate tests, describe the natural history of rare diseases and determine the safety and effectiveness of interventions to prevent disease or ameliorate its severity.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research.)

Elke Jordan,

Executive Secretary, National Advisory Council for Human Genome Research.

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Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, contact the SAMHSA Reports Clearance Officer at (301) 443–8005.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Mandatory Guidelines for Federal Workplace Drug Testing Program and Associated Forms—Extension of OMB approval will be requested for the Federal Custody and Control Form for Federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines, for the application and inspection forms for the National Laboratory Certification Program (NLCP), and for the reporting and recordkeeping language in the Guidelines. The Federal Custody and Control Form is used by all Federal agencies and employers regulated by the