

without first submitting a petition for rulemaking. All applicants using this one-step process must demonstrate that a suitable site exists which would comply with allotment standards with respect to minimum distance separation and city-grade coverage and which would be suitable for tower construction. To receive authorization for commencement of Digital Television ("DTV") operation, commercial broadcast licensees must file FCC Form 301 for a construction permit. This application may be filed anytime after receiving the initial DTV allotment but must be filed before mid-point in a particular applicant's required construction period. The Commission will consider these applications as minor changes in facilities. Applications will not have to supply full legal or financial qualification information.

On June 24, 2004, the U.S. Court of Appeals for the Third Circuit (the "Court") issued an Opinion and Judgment ("*Remand Order*") in which it upheld certain aspects of the Commission's new media ownership rules adopted on June 2, 2003 (*See* 18 FCC Rcd 13620 (2003)), specifically those dealing with local radio ownership, while requiring further explanation for all other aspects of the new rules. In particular, the Court held that the use of Arbitron Metro markets, the inclusion of noncommercial stations in determining radio market size, the attribution of joint sale agreements, and certain transfer restrictions are consistent with the Administrative Procedure Act. The Court stated that its prior stay of all new ownership rules would remain in effect pending the outcome of the remand proceeding. The Commission filed a petition for rehearing requesting that the Court lift the stay partially—*i.e.*, with respect to the radio ownership rules which the Court's *Remand Order* upheld. On September 3, 2004, the Court granted the Commission's petition, thus partially lifting the stay ("*Rehearing Order*"). As a result of the *Rehearing Order*, the new radio ownership rules took effect September 3, 2004.

Under the new radio ownership rules, radio Joint Sales Agreements (JSAs) are attributable and radio applicants are required to submit as a part of the FCC Form 301 a copy of any attributable JSA or time brokerage agreement.

*OMB Control Number:* 3060-0920.

*Title:* Application for Construction Permit for a Low Power FM Broadcast Station.

*Form Number:* FCC Form 318.

*Type of Review:* Extension of a currently approved collection

*Respondents:* Not-for-profit institutions; State, local or tribal government.

*Number of Respondents:* 2,283.

*Estimated Time Per Response:* 45 minutes to 6 hours.

*Frequency of Response:* On occasion reporting requirement.

*Total Annual Burden:* 6,315 hours.

*Total Annual Cost:* None.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* FCC Form 318 is required to apply for a construction permit for a new Low Power FM station, to make changes in the existing facilities of such a station, or to amend a pending FCC Form 318 application. The data is used by FCC staff to determine whether an applicant meets basic statutory and regulatory requirements to become a Commission licensee and to ensure that the public interest would be served by grant of the application.

*OMB Control Number:* 3060-0932.

*Title:* Application for Authority to Make Changes in a Class A TV Broadcast Station.

*Form Number:* FCC Form 301-CA.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit entities; Not-for-profit institutions; State, local or tribal government.

*Number of Respondents:* 650.

*Estimated Time per Response:* 7 hours.

*Frequency of Response:* On occasion reporting requirement.

*Total Annual Burden:* 4,550 hours.

*Total Annual Cost:* \$3,703,700.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* The FCC Form 301-CA is to be used in all cases by Class A television station licensees seeking to make changes in the authorized facilities of such station. The FCC Form 301-CA requires applicants to certify compliance with certain statutory and regulatory requirements. Detailed instructions provide additional information regarding Commission rules and policies.

On September 9, 2004, the Commission adopted a Report and Order, In the Matter of Parts 73 and 74 of the Commission's Rules to Establish Rules for Digital Low Power Television, Television Translator, and Television Booster Stations and to Amend Rules for Digital Class A Television Stations, FCC 04-220, MB Docket Number 03-185. To implement these rules, the Commission is revising FCC Form 301-CA to allow licensees to use the revised FCC Form 301-CA to

file for digital broadcast stations or conversion of their existing analog stations to digital stations.

Class A applicants are also subject to third party disclosure requirement of Section 73.3580 which requires local public notice in a newspaper of general circulation of the filing of all applications for major changes in facilities. This notice must be completed within 30 days of the tendering of the application. This notice must be published at least twice a week for two consecutive weeks in a three-week period. A copy of this notice must be placed in the public inspection file along with the application.

The FCC Form 301-CA is designed to track the standards and criteria which the Commission applies to determine compliance and to increase the reliability of applicant certifications.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 05-6561 Filed 4-1-05; 8:45 am]

**BILLING CODE 6712-01-P**

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## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the office of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 18, 2005.

**A. Federal Reserve Bank of Kansas City** (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Joel H. Wiens*, Cheyenne, Wyoming; to acquire voting shares of Union Bank Corporation, and thereby indirectly acquire voting shares of Union State Bank, both of Upton, Wyoming.

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

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

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

**BILLING CODE 6210-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

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

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

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

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

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

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

Its report, Coverage and Reimbursement of Genetic Tests and

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

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

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

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

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

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

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

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

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

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

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