

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 26, 2008.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *FA Capital, LLC, and Community Bank Investors of America, L.P.*, both of Richmond, Virginia, to acquire up to 58.01 percent of the voting securities of Freedom Bank, Bradenton, Florida.

Board of Governors of the Federal Reserve System, August 27, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8-20245 Filed 8-29-08; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Committee on Vital and Health Statistics: Meeting**

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Executive Subcommittee Meeting.

Time and Date: September 17, 2008, 12:45 p.m.-3:30 p.m.

Place: Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 505A, Washington, DC 20201.

Status: Open.

Purpose: The Executive Subcommittee will hold a strategic planning session, looking at roadmaps and plans for future activities including the 60th Anniversary of the NCHS.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of Committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: August 25, 2008.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. E8-20224 Filed 8-29-08; 8:45 am]

BILLING CODE 4151-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Committee on Vital and Health Statistics: Meeting**

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Time and Date: September 16, 2008 9 a.m.-3 p.m.; September 17, 2008 10 a.m.-12 p.m.

Place: Hubert H. Humphrey Building, 200 Independence Avenue, SW., Room 505A, Washington, DC 20201.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day the Committee will hear updates from the Department relating to Health HIT workforce needs, electronic health records, and personal health records; from the Center for Medicare and Medicaid Services and the Office of the National Coordinator. They will also work on a letter to the HHS Secretary regarding standards and security for e-prescribing standards. In the afternoon there will be a speaker on examples of technology for personal health records and an update from the National Conference for State Legislatures regarding HIT implementation in states.

On the morning of the second day the Committee will discuss subcommittee work. There will also be an update from NCHS Board of Scientific Counselors. In addition there will be a discussion of the NCVHS 60th Anniversary celebration and 21st Century Health Statistics update.

The times shown above are for the full Committee meeting. Subcommittee breakout sessions can be scheduled for late in the afternoon of the first day and second day and in the morning prior to the full Committee meeting on the second day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: August 26, 2008.

James Scanlon,

Deputy Assistant Secretary for Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. E8-20239 Filed 8-29-08; 8:45 am]

BILLING CODE 4151-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****Office of the Assistant Secretary for Planning and Evaluation; State Long-Term Care Partnership Program: State Reciprocity Standard**

AGENCY: Office of the Assistant Secretary for Planning and Evaluation (OASPE), HHS.

ACTION: Notice with Comment Period.

SUMMARY: Under section 6021 of Public Law 109–171, the Deficit Reduction Act of 2005 (DRA), States may provide asset disregards (and related estate recovery offsets) for Medicaid applicants who receive benefits under qualified long term care insurance policies (Partnership policies) that were purchased in the same State. This notice sets forth standards for states that choose to enter into a reciprocity agreement under section 6021(b) of the DRA, under which they agree to provide the same disregards and offsets for qualified Partnership policies that a Medicaid applicant purchased in another State that participates in the reciprocity agreement.

DATES: To be assured consideration, comments must be received at the address provided below, no later than 5 p.m. on November 3, 2008.

ADDRESSES: In commenting, please refer to file code ASPE–PLTC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this notice to <http://www.Regulations.gov>. Click on the link “Comment or Submission” and enter the keyword “PLTC–RS”. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Office of Disability, Aging, and Long-Term Care, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Attention: PLTC–RS, Hunter McKay, 200 Independence Avenue, SW., Room 424–E, Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address only: Office of Disability, Aging, and Long-Term Care, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, Attention: PLTC–RS, Hunter McKay, 200 Independence Avenue, SW., Room 424–E, Washington, DC 20201.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the

comment period to the following address: Room 424–E, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submitting Comments: We welcome comments from the public on all issues set forth in this notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code PLTC–RS and the specific “issue identifier” that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.Regulations.gov>. Click on the link “Comment or Submission” on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC, 20201, Monday through Friday of each week from 8:30 a.m. to 4 p.m.

The Department of Health and Human Services will also post communications from stake-holders, as they gain experience with the program, on the web-site for the Office of the Assistant Secretary for Planning and Evaluation: http://aspe.os.dhhs.gov/_/index.cfm.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can

access the database by using the World Wide Web; the Superintendent of Documents’ home page address is <http://www.gpoaccess.gov/>, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then login as guest (no password required).

FOR FURTHER INFORMATION CONTACT: Hunter McKay, (202) 205–8999.

SUPPLEMENTARY INFORMATION:**I. Legislative Background**

Medicaid is a joint Federal/State program established pursuant to title XIX of the Social Security Act. State Medicaid programs under title XIX generally cover medical and long-term care costs for certain people with limited income and resources, pursuant to “State Plans” approved by the Secretary of Health and Human Services (“the Secretary”). In general, individuals must have assets below a specified level in order to be eligible for Medicaid. Under certain circumstances, when a State calculates an applicant’s assets for purposes of determining Medicaid eligibility, the statute permits the State to disregard an amount equal to benefits paid to or on behalf of the individual under a qualifying long-term care insurance policy purchased in the same State. The statute also allows States to exempt benefits paid under the policy from Medicaid estate recovery after the insured’s death.

A State that wishes to apply this asset disregard must submit a Medicaid State Plan Amendment (SPA) for approval by the Secretary. The SPA creates a “Long-Term Care Partnership” (“Partnership”) and the long-term care policies that qualify for the asset disregard are referred to here as “Partnership policies.” States that have an approved SPA are referred to as “Partnership States.”

There are two types of Partnership States: those that had SPAs approved before May 14, 1993 (referred to here as “Original” Partnership States) and those that have submitted SPAs pursuant to section 6021 of the DRA (referred to here as “DRA” Partnership States).

Section 6021(b) of the DRA directs the Secretary to develop standards for Partnership States that wish to provide reciprocal disregards for Medicaid applicants who have purchased a qualified Partnership policy in another Partnership State. Section 6021(b) further provides that these standards must contain the following provisions:

- Benefits paid under such Partnership policies will be treated the same by all such States; and
- States with Partnership Programs established under the DRA shall be subject to these standards unless the State notifies the Secretary in writing of the State's election to be exempt

II. Reciprocity Standards in the Provision of a Medicaid Asset Disregard For Eligibility Determination and Estate Recovery

DRA Partnership States that have not elected (under section V, below) to be exempt from the reciprocity standards described below, and Original Partnership States that have elected to adopt such reciprocity standards (as described in Section VI below), are referred to here as "Participating States." Each Participating State agrees as follows:

1. Any individual who has purchased a Partnership policy in any Participating State; who has received benefits under the policy; and who applies for Medicaid in a Participating State other than the one in which the policy was issued, will receive an asset disregard in an amount equal (dollar for dollar) to the benefits received under the policy;

2. The asset disregard procedure and calculation will be the same for every individual with a Partnership policy that applies for Medicaid in the Participating State, without regard to whether the policy was purchased in another State, or the date the policy was purchased;

3. An amount equal to the benefits received under the Partnership policy will be exempt from Medicaid estate recovery provisions; and,

4. If a person moves from the State in which his or her Partnership policy was issued; later applies for Medicaid in another Participating State; and is determined to be eligible using a Partnership asset disregard, the Partnership asset disregard will not be revoked upon eligibility re-determination should the State subsequently decide to become exempt from the reciprocity agreement.

III. Other State Medicaid Eligibility Provisions Not Affected

These reciprocity standards only apply to the asset disregard described in Section II, above. Individuals who have received benefits under a Partnership policy, and qualify for an asset disregard, must meet all other Medicaid eligibility requirements in the State in which they are applying for Medicaid coverage. These may include requirements that relate to the Partnership policy, but only if those

requirements do not affect the asset disregard.

Example: Some Partnership States may require Medicaid applicants holding Partnership policies to exhaust all of the benefits under the policy before becoming eligible for Medicaid. Other Partnership States may allow applicants to apply for Medicaid coverage (and receive dollar for dollar asset disregard) even if residual benefits remain in the policy.

IV. Effective Date

These reciprocity standards will become effective on January 1, 2009.

V. Deemed Participation of States With Partnership Programs Established Under the DRA

As required by the statute, all DRA Partnership States will be deemed to be participating in the reciprocity agreement unless they elect to be exempt from the reciprocity standards by notifying the Secretary, in writing, of their election.

All States with State Plan Amendments effective dates prior to January 1, 2009, will be deemed to be participating in the reciprocity standards unless, prior to the effective date of these standards, the State elects exemption from the standards through a new SPA.

States with State Plan Amendment effective dates after January 1, 2009 will also be deemed to be participating in the reciprocity standards unless they elect exemption through a SPA.

VI. Participation by States Operating a Partnership Under the Authority of a State Plan Amendment Approved Prior to May 14, 1993

States with State Plan Amendments approved prior to May 14, 1993 may elect to adopt these reciprocity standards, and participate with those States operating a Partnership under the authority of the DRA. To do so, those States must submit a new SPA to that effect. Such States must agree to accept all of the reciprocity standards with respect to all other Participating States.

VII. Effect of Reciprocity Exemption

In order for a Medicaid applicant to be eligible for the asset disregard, both the State in which the individual is applying, and the State in which the Partnership policy was purchased, must currently be participating in the reciprocity standards. Accordingly, a State that elects an exemption from the reciprocity standards will not provide an asset disregard for Medicaid applicants who originally purchased Partnership policies in other, participating, Partnership States. Similarly, persons who originally

purchased Partnership policies in a State that elected exemption from the reciprocity standards will not be eligible for asset disregards in other Partnership States. Once a State elects exemption from the standards, the exemption applies regardless of when a Medicaid applicant originally purchased a Partnership policy in another State (i.e., even if the Medicaid applicant purchased the policy prior to the date on which a State elected exemption from the reciprocity standards).

VIII. Notice of Exemption by Currently Participating States

States that are currently participating in the reciprocity agreement agree that they will provide written notice to the Secretary at least 60 days prior to the effective date of electing an exemption from the reciprocity standards. The 60-day notification period makes it possible for the Department to notify other Participating States that, as of the effective date of withdrawal, asset disregards should no longer be made available to Medicaid applicants who originally purchased their policies in the State electing an exemption.

IX. Withdrawal of Reciprocity Exemption

A State which has elected exemption from the Partnership reciprocity standards may also withdraw its election at any point. A State may do so by submitting a new SPA. Once a State withdraws its election, the State agrees that reciprocity will be applied to all people holding Partnership policies regardless of when the policy was originally purchased.

X. Outside Agreements

There is nothing in these reciprocity standards which prohibits states from entering into reciprocity agreements with other states on a state-by-state basis, should they elect exemption from these reciprocity standards. The Department will create a communication mechanism for informing states and the public about which states have approved Partnership programs and which states are participating in these reciprocity standards.

XI. Change in Participation Status

States that wish to change their participation status should submit a new state plan amendment.

Dated: August 20, 2008.

Mary M. McGeein,

*Principal Deputy Assistant Secretary for
Planning and Evaluation.*

[FR Doc. E8-20225 Filed 8-29-08; 8:45 am]

BILLING CODE 4154-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-N-0166] (formerly
Docket No. 2006N-0238)

Maria Anne Kirkman Campbell; Denial of Hearing; Debarment Order

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Dr. Maria Anne Kirkman Campbell (Dr. Campbell) from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Campbell was convicted of a felony under Federal law for conduct relating to the development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the act. Dr. Campbell failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action. Even assuming that any statement in Dr. Campbell's correspondence with FDA were to be construed as requesting a hearing, Dr. Campbell has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action. Therefore, we are, in the alternative, issuing an order denying any such assumed request for a hearing because we find that there is no genuine and substantial issue of fact to grant a hearing on the debarment, if a hearing were requested.

DATES: This order is effective September 2, 2008.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brian Pendleton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304,

Silver Spring, MD, 20993-0002, 301-796-3504.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On March 25, 2004, the U.S. District Court for the Northern District of Alabama accepted Dr. Campbell's plea of guilty and convicted her of one count of mail fraud, a felony under 18 U.S.C. 1341 and 2. Specifically, Dr. Campbell admitted to submitting a fraudulent case report form (reflecting enrollment of a nonexistent person) while serving as a clinical investigator in a clinical study designed to test the safety and effectiveness of an antibacterial drug product, Ketek (telithromycin), for the treatment of respiratory tract infections. The clinical study was to be submitted to FDA in support of approval of Ketek.

Accordingly, in a letter dated February 28, 2007, and hand delivered on March 5, 2007, FDA served Dr. Campbell a notice proposing to permanently debar her from providing services in any capacity to a person having an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Dr. Campbell was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product. The letter offered Dr. Campbell an opportunity to request a hearing on the proposal, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action.

The letter also informed Dr. Campbell that her request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact requiring a hearing. In addition, the letter informed Dr. Campbell that the only material issue of

fact was whether she was convicted as alleged in the letter, and that the facts underlying her conviction are not at issue in this proceeding. The letter also informed Dr. Campbell that if it conclusively appeared from the face of the information and factual analyses in her request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, we would deny her request for a hearing and enter a final order of debarment. Finally, the letter informed Dr. Campbell that if she were to file a request for a hearing, she was required to file, on or before 60 days from the date of receipt of the letter, the information on which she relied to justify a hearing.

Dr. Campbell has responded to the proposal to debar her but has not requested a hearing.¹ Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

Even assuming that any statement in Dr. Campbell's correspondence with FDA were to be construed as requesting a hearing, Dr. Campbell has not submitted information that would justify granting a hearing. Therefore, we are, in the alternative, hereby denying any such assumed request for a hearing because Dr. Campbell has failed to show that there is a genuine and substantial issue of fact requiring a hearing. Dr. Campbell has not offered any information or factual analyses to refute that she was convicted of mail fraud for conduct relating to the development or approval of a drug product, or otherwise relating to the regulation of a drug product under the act.

II. Findings and Order

Therefore, the Associate Commissioner for Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act and under authority delegated to her, finds that Dr. Maria Anne Kirkman Campbell has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for

¹After we served Dr. Campbell on March 5, 2007, with notice of the agency's proposal to debar her, Dr. Campbell sent a series of letters to the agency—dated March 9, 2007, April 6, 2007, May 23, 2007, July 17, 2007, August 21, 2007, and January 13, 2008,—and participated in a teleconference with FDA on April 9, 2007. Although some of Dr. Campbell's correspondence refers to another proceeding the agency initiated against Dr. Campbell (investigator disqualification under 21 CFR 312.70), instead of, or in addition to, the proposal to debar her, for the purposes of this order, we have taken into account all of Dr. Campbell's correspondence with the agency after March 5, 2007, as well as the transcript from the April 9, 2007, teleconference.