

which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

\* \* \* \* \*

**PERSON TO CONTACT FOR INFORMATION:**

Judith Ingram, Press Officer; Telephone: (202) 694-1220.

**Shawn Woodhead Werth,**

*Commission Secretary and Clerk.*

[FR Doc. 2016-16268 Filed 7-6-16; 11:15 am]

**BILLING CODE 6715-01-P**

---

**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 will also 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.

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 August 4, 2016.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528. Comments can also be sent electronically to

[Comments.applications@rich.frb.org](mailto:Comments.applications@rich.frb.org):

1. *BNC Bancorp*, High Point, North Carolina; to acquire 100 percent of the voting shares of High Point Bank Corporation, High Point, North Carolina, and thereby indirectly acquire High

Point Bank and Trust Company, High Point, North Carolina.

Board of Governors of the Federal Reserve System, July 5, 2016.

**Margaret Shanks,**

*Deputy Secretary of the Board.*

[FR Doc. 2016-16255 Filed 7-7-16; 8:45 am]

**BILLING CODE 6210-01-P**

---

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**[Document Identifiers: CMS-10137, CMS-10237 and CMS-379]**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by September 6, 2016.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options"

to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10137 Solicitation for Applications for Medicare Prescription Drug Plan 2018 Contracts  
 CMS-10237 Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits  
 CMS-379 Financial Statement of Debtor

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this

requirement, CMS is publishing this notice.

### Information Collection

#### 1. Type of Information Collection

**Request:** Revision of a currently approved collection; **Title of Information Collection:** Solicitation for Applications for Medicare Prescription Drug Plan 2018 Contracts; **Use:** Coverage for the prescription drug benefit is provided through contracted prescription drug (PD) plans or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under section 1876 of the Social Security Act, and Employer Group Waiver Plans may also provide a part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates, and receive final approval from CMS. Existing part D Sponsors may also expand their contracted service area by completing the Service Area Expansion application. **Form Number:** CMS-10137 (OMB control number: 0938-0936); **Frequency:** Yearly; **Affected Public:** Private sector (Business or other For-profits and Not-for-profit institutions); **Number of Respondents:** 463; **Total Annual Responses:** 160; **Total Annual Hours:** 1,565. (For policy questions regarding this collection contact Arianne Spaccarelli at 410-786-5715.)

#### 2. Type of Information Collection

**Request:** Revision of a currently approved collection; **Title of Information Collection:** Applications for part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide part C Benefits; **Use:** This information collection includes the process for organizations wishing to provide healthcare services under MA and/or MA-PD plans must complete an application annually, file a bid, and receive final approval from CMS. The application process has two options for applicants that include: Request for new MA product or request for expanding the service area of an existing product. This collection process is the only mechanism for MA and/or MA-PD organizations to complete the required application process. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the Medicare Advantage program and to make a decision related to contract award. **Form Number:** CMS-10237 (OMB control number: 0938-0935); **Frequency:** Yearly; **Affected Public:** Private sector (Business or other For-

profits and Not-for-profit institutions); **Number of Respondents:** 310; **Total Annual Responses:** 310; **Total Annual Hours:** 10,941. (For policy questions regarding this collection contact Marcella Watts at 410-786-5724.)

#### 3. Type of Information Collection

**Request:** Extension of a currently approved collection; **Title of Information Collection:** Financial Statement of Debtor; **Use:** Section 1893(f)(1) of the Social Security Act and 42 CFR 401.607 provides the authority for collection of this information. Section 42 CFR 405.607 requires that, CMS recover amounts of claims due from debtors including interest where appropriate by direct collections in lump sums or in installments. In addition, the DOJ Final Rule, the Federal Claims Collection Standards, which was published as 32 CFR parts 900-904, on November 22, 2000, in the **Federal Register**, section 32 CFR 900.1 stipulates that, standards for Federal agency use in the administrative collection, offset, compromise, and the suspension or termination of collection activity. Section 32 CFR 901.8(a) states that, Agencies should obtain financial statements from debtors who represent that they are unable to pay the debt in one lump sum. **Form Number:** CMS-379 (OMB control number: 0938-0270); **Frequency:** Yearly; **Affected Public:** Private sector (Business or other for-profits); **Number of Respondents:** 500; **Total Annual Responses:** 500; **Total Annual Hours:** 1,000. (For policy questions regarding this collection contact Anita Crosier at 410-786-0217.)

Dated: July 5, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2016-16220 Filed 7-7-16; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-D-1233]

#### Use of Public Human Genetic Variant Databases To Support Clinical Validity for Next Generation Sequencing-Based In Vitro Diagnostics; Draft Guidance for Stakeholders and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing the availability of the draft guidance entitled “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics.” This draft guidance document describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA’s regulatory review of next generation sequencing (NGS)-based tests. This draft guidance further outlines the process by which administrators of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 6, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).