

proposed by FDA, and information on reference databases; an open public comment session; and an open discussion on selected topics raised by the presentations (see section III of this document.) During the discussions, the participants will not be asked to develop consensus opinions but rather to provide their individual perspectives.

Additional information, including a meeting agenda, will be available on the Internet, immediately after publication of this document in the **Federal Register**. The evaluation approach proposed by FDA is expected to be available at a later date. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at <http://www.regulations.gov>. This information will also be available at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

III. Topics for Input

FDA will seek input on its proposed performance evaluation approach, which will include the following topics:

1. *Clinical Application of Highly Multiplexed Microbiology Devices:* Their clinical application and public health/clinical needs; inclusion of MCM-related pathogens that are expected to be rarely present in the tested specimens; the composition of clinically relevant panels of pathogens; the interpretation of the test results taking into consideration the possible detection of microorganisms that are not clinically relevant, and what is known and unknown about co-infections.

2. *Device Evaluation:* How to evaluate the analytical and clinical performance of highly multiplexed microbiology devices; approaches to device validation when positive specimens are not easily available, which is the case for many MCM pathogens; sufficiency, feasibility, and practicality of the proposed FDA evaluation approach to establish device performance.

3. *Reference Databases:* Quality criteria for establishing the accuracy of

reference databases; methods for curating, maintaining, and updating these databases; what is the current practice for creating and maintaining reference databases.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., rm. 1050, Rockville, MD 20857.

Dated: August 2, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail

paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency; (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: National Health Service Corps Site Application (OMB No. 0915-0230)—Revision

The National Health Service Corps (NHSC) of the Bureau of Clinician Recruitment and Service (BCRS), Health Resources and Services Administration, is committed to improving the health of the Nation's underserved by uniting communities in need with caring health professionals, and by supporting their efforts to build better systems of care. The NHSC Site Application, which renames and revises the previous Recruitment and Retention Assistance Application, requests information on the clinical service site, sponsoring agency, recruitment contact, staffing levels, service users, charges for services, employment policies, and fiscal management capabilities. Assistance in completing the application may be obtained through the appropriate State Primary Care Offices, State Primary Care Associations and the NHSC. The information on the application is used for determining the eligibility of sites for assignment of NHSC-obligated health professionals and to verify the need for NHSC clinicians. Approval as an NHSC service site is good for 3 years; sites wishing to remain eligible for assignment of NHSC providers must submit a new Site Application every 3 years.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
NHSC Site Application	3000	1	3000	0.5	1500

E-mail comments to paperwork@hrsa.gov or mail to the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 30 days of this notice.

Dated: August 2, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA

Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (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: National Sample Survey of Nurse Practitioners (OMB No. 0915-xxxx)-[NEW]

The number of Nurse Practitioners (NP) in the United States has been growing rapidly over the past decade and continued growth is expected as the annual number of graduates of NP programs is at an all time high. Furthermore, over the past 20 years, many regulatory and financial barriers to using NPs have been removed. The expansion of health insurance under the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) will also increase the demand for services. With increasing numbers, NPs are poised to play a critical role in the nation's efforts to expand access to health care services.

Despite the increasing number and role of NPs, unfortunately, there is currently only limited, inconsistent data available to policy makers and the health care community. Accordingly, it is difficult for these leaders to quantify

or fully understand the role of NPs in the current or future health care system. In fact, it is difficult to project with confidence the number of NPs practicing in the United States today.

The primary purpose of the Bureau of Health Professions' National Sample Survey of Nurse Practitioners data collection is to: (1) Improve estimates of NPs providing services; (2) describe the settings where NPs are working; (3) identify the positions/roles in which NPs are working; (4) describe the activities and services NPs are providing in the healthcare workforce; (5) determine the specialties in which NPs are working; (6) explore NPs' satisfaction with and perception of the extent to which they are working to their full scope of practice; and (7) assess variations in practice settings, positions, and practice patterns by demographic and educational characteristics.

The statutory provision that authorizes this data collection is section 761 of the Public Health Service Act, "Health Professions Workforce Information and Analysis," which is codified at 42 U.S.C. 294n. The information obtained from this survey will ultimately lead to more accurate and complete national estimates of the current NP supply, as well as assist in the development of more accurate supply and demand projections for NPs. This, in turn, is likely to influence decisions regarding both the educational capacity and the number of NP programs at the national level.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
National Sample Survey of Nurse Practitioners	10,000	1	10,000	.33	3,300
Total	10,000	10,000	3,300

E-mail comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 2, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Use of PKM2 Activators for the Treatment of Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is

contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Provisional Patent Application No. 61/104,091, entitled "Activators of Human Pyruvate Kinase," filed October 9, 2008, now abandoned [HHS Ref. No. E-326-2008/0-US-01]; PCT/US2009/60237 Application entitled "Small Molecule Activators of Pyruvate Kinase," filed October 9, 2009, now abandoned [HHS Ref. No. E-326-2008/0-PCT-02]; EP Application No. 09740795.1, entitled "Small Molecule Activators of Pyruvate Kinase," filed October 9, 2009 [HHS Ref. No. E-326-2008/0-EP-05]; U.S. Non-Provisional Application No. 13/123,297, entitled