Request for Comment

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before March 19, 2018. Write ''FPLA Rules, PRA Comment, P074200'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at *http://www.ftc.gov/os/publiccomments.shtm*.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/fplaregspra2,* by following the instructions on the web-based form. When this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that website.

If you file your comment on paper, write ''FPLA Rules, PRA Comment, P074200'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at *https://www.ftc.gov/,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which * * * is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 19, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy*. For supporting documentation and other information underlying the PRA discussion in this Notice, see *http://www.reginfo.gov/public/jsp/PRA/praDashboard.jsp*.

Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead can also be sent by email to *wliberante@omb.eop.gov*.

David C. Shonka,

Acting General Counsel.

[FR Doc. 2018–03289 Filed 2–15–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: Through this Request for Information (RFI), the Agency for Healthcare Research and Quality (AHRQ) is seeking information from the public, hospitals and other health care organizations, clinicians, quality improvement experts, researchers, and quality measure developers about current use of the AHRQ Quality Indicators (AHRQ QIs) for quality improvement efforts. AHRQ recognizes that the AHRQ QIs have been adopted for other uses, but for the purpose of this RFI, the Agency is specifically seeking information about quality improvement initiatives such as those that seek to: Improve clinical practice (*e.g.,* adherence to guidelines, coordination of care); improve patient safety or reduce harm; address disparities in health or care; improve prevention practices; and collaborate with community groups to improve health or care. AHRQ is also seeking information about the ways in which the Agency can increase use of the AHRQ QI measures for quality improvement, for example by refining measures, summarizing best practices, creating training materials, developing standardized metrics, and/or convening learning networks. To learn more about the AHRQ QIs, visit *https://www.qualityindicators.ahrq.gov/*.

DATES: Comments on this notice must be received by the deadline on or before March 8, 2018.

ADDRESSES: Written comments should be submitted to: Maushami DeSoto, Ph.D., MHA, Health Scientist Administrator, Center for Delivery Organization and Markets, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email at *Maushami.Desoto@ahrq.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Maushami DeSoto, Ph.D. MHA, Health Scientist Administrator, (301) 427–1546, or by emails at *Maushami.Desoto@ahrq.hhs.gov*.

SUPPLEMENTARY INFORMATION: The mission of AHRQ is to produce evidence to make health care safer; higher quality; and more accessible, equitable, and affordable. AHRQ works within the U.S. Department of Health and Human Services and with other public and private partners to make sure that the evidence is understood and used. The Agency fulfills this mission by supporting and conducting research; generating needed evidence; disseminating proven practices; creating and distributing training materials for health care systems and professionals; and developing measures and data used to track and improve performance. To learn more about the Agency, visit *https://www.ahrq.gov/*.

Background

Over the years, use of the AHRQ QIs has evolved. Originally developed to support quality improvement at the hospital and community levels, the AHRQ QIs now serve several additional purposes including: (1) Research; (2) needs assessments for planning at the local, state, and national levels; and (3) performance assessment by private and public value-based payment and consumer choice programs. In the current context, in which the purposes and methods of measurement continue to change rapidly, AHRQ is seeking updated information to inform its own planning and priority setting for future work in the area of measures for quality improvement. To do so, AHRQ must define evidence criteria that are specific to quality improvement and use those criteria to determine which AHRQ QIs work best for quality improvement and how they can be improved for that purpose.

As part of this effort, AHRQ is conducting a literature review and environmental scan to: (1) Document knowledge and evidence on the scientific acceptability of the AHRQ QIs for quality improvement; (2) document and synthesize information about the strengths and limitations of the AHRQ QIs; (3) identify areas of disagreement, if any, in the evidence; and (4) develop suggestions for refinement or improvement in the indicators, particularly those that make the AHRQ QIs more useful for quality improvement. As part of the environmental scan, AHRQ is issuing this RFI to obtain information from stakeholders who have not published their experiences using the AHRQ QIs or who wish to provide additional information beyond what they have published. AHRQ will review results from the literature review and environmental scan and release a summary report in December 2018.

Specific questions of interest to the Agency include, but are not limited to:

For Hospitals or Other Health Care Entities That *CURRENTLY USE* AHRQ QIs for Quality Improvement:

1. What type of organization do you represent?
2. How does your organization define quality improvement?
3. How does your organization use the AHRQ QIs for quality improvement? For example, do you use them for identifying patient safety problems, identifying quality improvement opportunities, and/or tracking performance over time?
4. Which specific AHRQ QIs does your organization use for quality improvement? Please include the number of each QI, for example, PQI 05, which can be found at the AHRQ QI website.
5. Have you stopped using an AHRQ QI for quality improvement? If yes, please identify it and explain why you stopped.
6. Of the AHRQ QIs you use now or used previously, which ones have been most valuable in improving quality?
   a. What are the strengths of each measure you have used?
   b. What are the weaknesses of each measure you have used?
7. What other methodological and/or data quality issues have you encountered when using AHRQ QIs for quality improvement that you haven't already mentioned?
8. Does your organization use measures other than the AHRQ QIs for quality improvement? If yes, which ones and what types of quality improvement initiatives does your organization use them for? How do they compare to the AHRQ QIs in terms of ease of use and impact on quality?
9. What changes and refinements to the AHRQ QIs would make them easier to use for quality improvement?
10. What changes and refinements to the AHRQ QIs would make them more effective for improving quality?
11. What resources would aid the uptake of the AHRQ QIs for quality improvement?
12. What improvements are needed to current AHRQ QI resources? These include resources available through the QI website such as tool kits, case studies, webinars, presentations, publication lists, video tutorials (WinQI and SASQI), measure technical specifications (IQI, PQI, PSI, PDI), TA support, FAQs, and software.
13. If you operate a community health center, which AHRQ QIs do you use for quality improvement in the community health center? Which other measures do you use for quality improvement in the community health center?
14. If you operate a hospital emergency department (ED), which AHRQ QIs do you use for quality improvement in the ED? Which other measures do you use for quality improvement in the ED?

For Hospitals or Other Health Care Entities That Are *NOT CURRENTLY USING* Any AHRQ QIs for Quality Improvement:

15. How does your organization define quality improvement?
16. What types of quality improvement initiatives does your organization engage in?
17. Have you heard of the AHRQ QIs? If yes, what do you know about them?
18. What factors contribute to your organization's decision to not use the AHRQ QIs?
19. Has your organization used the AHRQ QIs in the past? If so, why is your organization no longer using them?
20. What measures does your organization use for quality improvement? What are some of the reasons/factors your organization uses these measures?
21. If you operate a community health center, which measures do you use for quality improvement?
22. If you operate a hospital emergency department (ED), which measures do you use for quality improvement?
23. If your organization is a community health center, which metrics do you use for quality improvement?
24. If your organization is an ED which metrics do you use for quality improvement and monitoring?

AHRQ is interested in all the questions listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed. AHRQ will use the information it receives to assist in developing future initiatives. These initiatives may include, but are not limited to, developing research grant and contracting opportunities, investing in the creation of tools and training materials for health professionals and health care delivery organizations, developing quality improvement measures, and/or convening learning collaboratives.

Health care professionals and organizations are encouraged to respond to this RFI by submitting a written statement and supporting explanatory materials to the email or mailing address listed above by February 28, 2018. Supporting materials might include charters for quality and safety improvement committees, data use agreements for learning collaboratives, population health metrics and reports, or guidelines for the use of evidence-based practices. When responding to questions listed above, please clearly indicate the number of the question that is being addressed. AHRQ encourages respondents to include a description of their health care delivery organization at the beginning of their response to provide context for the information they provide.

Request for Comments

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas identified in response to it. AHRQ will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, responses to the RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports. Respondents will not be identified in any published reports. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s). The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public.

Gopal Khanna,

Director.

[FR Doc. 2018–03243 Filed 2–15–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–3856; FDA–2015–E–3857]

Determination of Regulatory Review Period for Purposes of Patent Extension; MOVANTIK

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MOVANTIK and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 17, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 17, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 17, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 15, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA 2015–E–3856 and FDA 2015–E–3857 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; MOVANTIK.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the