

agency or other federal entity that furnished the record or information for the purpose of permitting that agency or entity to make a decision regarding access to or correction of the record or information, or to a federal agency or entity for purposes of providing guidance or advice regarding the handling of a particular request.

3. A record from this system of records may be disclosed to the Department of Justice (DOJ) to obtain advice regarding statutory and other requirements under the FOIA.

4. A record from this system of records may be disclosed to the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h) to review administrative agency policies, procedures, and compliance with the FOIA, and to facilitate OGIS's offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

None.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in paper and electronic form, including on computer databases, all of which are stored in a secure location.

**RETRIEVABILITY:**

Records are retrieved by any one or more of the following: The name of the requestor; the number assigned to the request or appeal; and in some instances, the name of the attorney representing the requestor or appellant, and/or the name of an individual who is the subject of such a request or appeal.

**SAFEGUARDS:**

FRTIB has adopted appropriate administrative, technical, and physical controls in accordance with FRTIB's security program to protect the security, confidentiality, availability, and integrity of the information, and to ensure that records are not disclosed to or accessed by unauthorized individuals.

Paper records are stored in locked file cabinets in areas of restricted access that are locked after office hours. Electronic records are stored on computer networks and protected by assigning usernames to individuals needing access to the records and by passwords set by unauthorized users that must be changed periodically.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of in accordance with the General Records Schedule 4.2, item 020, issued by the National Archives and Records Administration (NARA).

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief FOIA Officer, 77 K Street NE., Washington, DC 20002.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether this system of records contains information about themselves must submit a written request to the FOIA Officer, FRTIB, 77 K Street NE., Washington, DC 20002, and provide the following information:

- a. Full name;
- b. Any available information regarding the type of record involved;
- c. The address to which the record information should be sent; and
- d. You must sign your request.

Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual, such as a Power of Attorney, in order for the representative to act on their behalf. Individuals requesting access must also comply with FRTIB's Privacy Act regulations regarding verification of identity and access to such records, available at 5 CFR part 1630.

**RECORD ACCESS PROCEDURE:**

Same as Notification Procedures.

**CONTESTING RECORDS PROCEDURE:**

Same as Notification Procedures.

**RECORD SOURCE CATEGORIES:**

Records are obtained from those individuals who submit requests and administrative appeals pursuant to the FOIA or who file litigation regarding such requests and appeals; the agency record keeping systems searched in the process of responding to such requests and appeals; FRTIB employees assigned to handle such requests, appeals, and/or litigation; other agencies or entities that have referred to FRTIB requests concerning FRTIB records, or that have consulted with FRTIB regarding handling of particular requests; and submitters or subjects of records or information that have provided assistance to FRTIB in making access or amendment determinations.

**EXEMPTIONS CLAIMED FOR SYSTEM:**

None.

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**BILLING CODE 6760-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Agency for Healthcare Research and Quality**

**Request for Measures Assessing Health Care Organization Quality Improvement Activities To Improve Patient Understanding, Navigation, Engagement, and Self-Management**

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), DHHS.

**ACTION:** Notice of request for measures.

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) requests information from the public (including health care delivery organizations, health information developers, payers, quality measure developers, clinicians, and health care consumers) about quality improvement measures designed to help health care organizations monitor initiatives aimed at:

- Improving patient understanding of health information,
- simplifying navigation of health care systems and facilities, and
- enhancing patients' ability to manage their health.

Specifically, AHRQ seeks quality improvement measures in four domains:

1. Communication,
2. Ease of Navigation,
3. Patient Engagement and Self-Management, and
4. Organizational Structure, Policy, and Leadership.

AHRQ is interested in measures that do not require patient survey data and that health care organizations are currently using, or have used in the past, to guide quality improvement activities designed to address these domains. AHRQ is also interested in information about relevant measures that are under development or are suggested for future development.

**DATES:** Please submit one or more quality improvement measures and supporting information on or before March 4, 2016. AHRQ will not respond individually to submitters, but will consider all submitted measures and publicly report the results of the review of the submissions in aggregate.

**ADDRESSES:** Submissions should follow the Submission Instructions below. Electronic responses are preferred and should be addressed to [HealthLiteracy@AHRQ.HHS.gov](mailto:HealthLiteracy@AHRQ.HHS.gov). Non-electronic responses will also be accepted. Please send these by mail to: Cindy Brach, Center for Delivery, Organization, and Markets, Agency for Healthcare Research and Quality, 5600 Fisher Lane, Rockville, MD 20857, Mailstop: 07W25B.

**FOR FURTHER INFORMATION CONTACT:**

HealthLiteracy@AHRQ.HHS.gov or  
Cindy Brach at the address above.

**SUPPLEMENTARY INFORMATION:****Background Information**

The health care system is complex and demanding. Health care organizations can help patients to succeed in the health care environment by ensuring that patients and caregivers are able to understand health information, navigate the health care system, engage in the health care process, and take an active and effective role in the management of their health.

This Request for Measures is part of a project that aims to:

- Identify existing measures that organizations use or could use to monitor progress related to the four domains described above; and,
- Refine and cull identified measures to establish a set of measures that reflects patient priorities, has expert support, and will be recommended for more formal measure development and testing.

The project focuses on identifying measures that are not generated from patient survey data.

The project is guided by a conceptual framework that builds on the concept of organizational health literacy. As described in the Institute of Medicine's Roundtable on Health Literacy, organizational health literacy is the "implementation and monitoring of organizational policies, practices, and structures that support patients in understanding health information, navigating the health care system, and managing their health" (Brach et al. 2012). The conceptual framework identifies four domains as key components of organizational health literacy.

1. Communication (e.g., the quality of verbal and written communication with patients, families, caregivers)
2. Ease of Navigation (e.g., the degree to which an organization's physical environment and systems of care are designed in a manner that simplifies navigation and use of services)
3. Patient Engagement and Self-Management (e.g., the degree to which an organization encourages patient engagement and provides support to enhance the ability of patients to manage their health)
4. Organizational Structure, Policy, and Leadership (e.g., leadership support for organizational health literacy; implementation of policies, procedures, and structures that serve to improve communication with patients, simplify patient navigation, and enhance patient engagement and self-management)

Quality improvement measures selected for further measure development and testing will assess key features of one or more of these domains.

This project is being conducted by AHRQ pursuant to its statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(2).

**Submission Guidance**

Submit a measure(s) that is currently in use, in development, or for which a need has been identified, in one or more of the four domains (i.e., Communication; Ease of Navigation; Patient Engagement and Self-Management; and Organizational Structure, Policy, and Leadership). For this Request for Measures, AHRQ is specifically interested in measures that do not require or use patient reported data obtained using a patient survey.

Your contribution will be very beneficial to AHRQ. 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. Materials that are considered confidential and marketing materials cannot be used by AHRQ. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

AHRQ and its contractor, will evaluate all submitted measures and supporting documentation. As a set of measures is identified and evaluated for further refinement and testing, submissions may be included in whole or in part or may be modified for inclusion in the measurement set. AHRQ will assume responsibility for the final measurement sets as well as any future modifications.

**Submission Instructions**

To facilitate handling of submissions, please include the name and email address of the measure developer or contact.

The responses most helpful to the Agency will include all or most of the following:

1. A brief cover letter,
2. a description of the measure and how it is calculated (e.g., who/what is included in the numerator, who/what is included in the denominator, who/what is excluded in calculating the measure),
3. the source of the measure (e.g., publications, organizations where measure has been used to guide quality improvement activities),

4. the domain best aligned with the measure (i.e., Communication; Ease of Navigation; Patient Engagement and Self-Management; and Organizational Structure, Policy, and Leadership),

5. the source of data used to calculate the measure (e.g., electronic health records, internal monitoring and reporting systems),

6. a description of data collection strategies (e.g., who is responsible for data collection, how is the information needed to calculate the measure collected),

7. a list of health care settings in which the measure has been or would be used and characteristics of the patient populations in these health care settings,

8. a description of how the measure has been used to support performance improvement (e.g., to whom is the measure reported, what actions have been taken based on the measure),

9. a summary of unintended negative consequences resulting from use of the measure (e.g., evidence that implementation of the measure has negatively impacted patients, staff, clinical process, or other features of the implementing organization), and

10. evidence that the measure is:

- a. Valid and reliable,
- b. associated with important outcomes,
- c. meaningful to patients, families, clinicians, and/or administrators,
- d. feasible to compute with accuracy and without undue cost, burden, or delay, and
- e. generalizable across health care settings.

11. title, author(s), publication year, journal name, volume, issue, and page numbers of cited articles.

12. a statement of willingness to grant to AHRQ the right to use and disseminate submitted measures and their documentation to the public as part of a set of organizational health literacy measures.

Submission of copies of existing documentation or reports describing the measure and its properties, existing data sources, etc. is highly desirable but not required.

**Reference Material**

- Brach, C., Keller, D., Hernandez, L.M., et al. (2012). Ten attributes of a health literate health care organization. Washington DC: Institute of Medicine.
- Kripalani, S., Wallston, K., Cavanaugh, K.L., Osborn, C., Mulvaney, S., Scott, A.M., & Rothman, R.L. (2014). Measures to assess a health-literate organization.

Washington DC: Institute of Medicine.

**Sharon B. Arnold,**

*Deputy Director.*

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**BILLING CODE 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:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: *“Making It Easier for Patients to Understand Health Information and Navigate Health Care Systems: Developing Quality Improvement Measures.”* In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

**DATES:** Comments on this notice must be received by April 11, 2016.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

*Making It Easier for Patients To Understand Health Information and Navigate Health Care Systems: Developing Quality Improvement Measures*

A goal of Healthy People 2020 is to increase Americans’ health literacy,

defined as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”<sup>1</sup> The effects of limited health literacy are numerous and serious, including medication non-adherence resulting from patients’ inability to read and comprehend medication labels; underuse of preventive measures, such as vaccines; poor self-management of conditions such as asthma and diabetes; and higher utilization of inpatient and emergency department care. According to the 2003 National Assessment of Adult Literacy, 88% of U.S. adults have significant difficulties understanding widely used health information. By adopting “health literacy universal precautions,” health care providers and organizations can create an environment in which all patients—regardless of health literacy level—can successfully (1) understand health information, (2) navigate the health care system, (3) engage in medical decision-making, and (4) manage their health.

Numerous resources have been developed to support health care organizations in their attempts to address limitations in patient health literacy. However, little work has been done to establish valid quality improvement measures that organizations can use to monitor the impact of initiatives aimed at improving patient understanding, navigation, engagement, and self-management. Absent such measures, organizations may be unable to accurately assess whether their initiatives are effective.

This research has the following goals:

1. Identify existing quality improvement measures and gather proposals for additional measures (not generated from patient survey data) that organizations may use to monitor progress related to enhancing patient understanding, navigation, engagement, and self-management; and
2. Identify a set of quality improvement measures that reflect patient priorities, has expert support, and can be recommended for more formal measure development and testing.

This project is being conducted by AHRQ through its contractor, Board of Regents of the University of Colorado, pursuant to AHRQ’s statutory authority

to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

**Method of Collection**

**Environmental Scan Interviews:** Representatives from 25 health care organizations engaged in relevant quality improvement efforts will be interviewed to obtain information about the quality improvement measures they use in assessing their work to improve patient understanding, navigation, engagement, and self-care.

The planned environmental scan interviews will provide the information needed to:

- Identify and document the characteristics of relevant quality improvement measures that are already in use; and
- identify additional measures that would be useful to stakeholders in the field.

The findings from these interviews will be used, along with the results from other activities (*i.e.*, input from a Technical Expert Panel, literature review, a Request for Information published in the **Federal Register**, and focus groups with patients), to identify and document a set of quality improvement measures that can be recommended for rigorous testing and validation. Measures that are assessed to be valid and reliable will be eligible to be disseminated by AHRQ to support health care organizations in their efforts to improve patient understanding of health information, navigation of the health care system, engagement in medical decision-making, and management of their health.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the respondents’ time to participate in Environmental Scan Interviews. The Environmental Scan Interviews will be completed by 50 respondents (2 representatives from each of the 25 organizations targeted for participation).

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Environmental Scan Interviews .....	50	1	2	100