

SUPPORTING STATEMENT

Part A

**American Recovery and Reinvestment Act
“Registry of Patient Registries”
Contract No. HHSA290201400004C**

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Agency for Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that Make the Collection of Information Necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see <http://www.ahrq.gov/hrqa99.pdf>), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and
2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and
3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

In line with the organization's goals, AHRQ has developed the Registry of Patient Registries (RoPR). By providing a centralized point of collection for information about all patient registries in the United States, the RoPR furthers AHRQ's goals by enhancing patient registry information, extracted from ClinicalTrials.gov or modeled based on the ClinicalTrials.gov data elements, to further describe the quality, appropriateness, and effectiveness of health services (and patient registries in particular) in a more readily available, central location.

AHRQ is now proposing the development of the Outcome Measure Repository (OMR), a web-based database intended to house detailed information about outcome measures currently used in patient registries. This system will be linked to RoPR in two key ways. First, users entering registry information in the RoPR system will be able to associate OMR measure records with the RoPR registry records. Second, measure stewards listing a measure record in the OMR system will be able to associate the measure with an existing RoPR patient registry. Users will be able to access both databases with a single account (i.e., users with a RoPR account will be able to log in/access the OMR using that account, and vice versa).

The OMR database system aims to achieve the following objectives:

- 1) Provide a searchable database of outcome measures used in patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);
- 2) Facilitate the use of standardized data elements and outcome measures;
- 3) Facilitate the identification of potential areas of harmonization;

To achieve the three objectives of this project, the following data collections will be implemented:

- 1) Collect information on outcome measures and related sub-elements from measure stewards who populate the OMR database system.

The new OMR database is being developed by AHRQ through its contractor, L&M Policy Research and subcontractors Truven Health Analytics, an IBM Company, and OM1, 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 outcomes, cost, cost-effectiveness, and use of health care services and access to such services, and with respect to health statistics and database development. 42 U.S.C. 299a(a)(3) and (8).

2. Purpose and Use of Information

The purpose of the OMR is to provide a readily available public resource that houses definitions of outcome measures associated with patient registries. The information being collected in each OMR record will be visible to the public visiting the OMR website and readily available for public use.

Users of the OMR will primarily fall into two types: those stewarding a registry who will provide information on the data they collect in their registry, and those who will search for information about how a particular type of outcome measure is collected within patient registries. For the OMR to succeed, the first group of users – registry stewards – must be able to enter information into the system easily and efficiently. The second group of users – parties interested in seeking information on outcome measures – must be able to find sufficient information efficiently on outcome measures to identify items for use in their own registry or research. Meeting the needs of both sets of users is an important consideration in the design of the OMR.

3. Use of Improved Information Technology

The OMR is web-based, and does not require users to submit any type of paper forms. As the OMR is affiliated with and connected to the existing RoPR system, it will use the same web-based data collection system. Users will enter information into the web-based system manually, through an intuitive and logical step-by-step data entry process. Whenever applicable, the system allows for users to select from check box, radio button,

or dropdown menu options. The results of information collection will be available to the public online, via the OMR website.

4. Efforts to Identify Duplication

Patient registry information, including limited information about outcome measures, is collected by ClinicalTrials.gov. However, because registration in ClinicalTrials.gov is not currently mandated for registries and observational studies, the information that ClinicalTrials.gov collects is not completely sufficient for the needs of users registering information about existing patient registries and related measures. For example, the only measure-related fields collected in ClinicalTrials.gov are title, time frame, and description. The OMR will collect additional details about measures (e.g., precise sub-element definitions, numerators, and denominators) that will better facilitate the identification and adoption of standardized measures across patient registries.

The National Library of Medicine's (NLM) Common Data Element (CDE) Repository is an existing resource designed to provide access to structured data element definitions recommended by National Institutes of Health (NIH) Institutes and Centers and other organizations for use in research. Currently, the CDE Repository includes data elements that may contribute to a measure definition, but does not contain complete measure information. Distinctly, the OMR will group data elements at a higher level, as components of outcomes measures. The OMR design and development team will collaborate with NLM to align the OMR and CDE repositories, apply CDE tools and best practices to the OMR, and facilitate the incorporation of OMR records into the CDE resource portal.

5. Involvement of Small Entities

While small businesses and other small entities may use the OMR to enter information, participation is not compulsory. The information being requested by the OMR is held to the absolute minimum required for the intended use. It is not expected that small businesses need to provide less information than any other business or entity registering a registry in the OMR. The burden is voluntary and minimal, and therefore should not be taken into consideration.

6. Consequences if Information Collected Less Frequently

If the OMR ceases to collect the measure information it is intended to collect, then outcome measure information will continue to be stored and accessed as it is currently: in a fragmented and inconsistent way that does not facilitate collaboration among researchers and other stakeholders, reduced redundancy in research, and improved transparency in registry practice.

Because participation in the OMR is not obligatory, it is possible that collection from a given entity may only occur once, or less frequently than recommended. Measure stewards may choose to only post information regarding an outcome measure one time,

expecting users to seek them out for updated data.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on Page 4053 of Federal Register, Volume 83, Number 19, Monday, January 29, 2018 for 60 days (see Attachment A).

8.b. Outside Consultations

The structure of the OMR system is based on the Outcome Measures Framework Information Model Report developed by AHRQ and its contractor, L&M Policy Research and subcontractors OM1 and Quintiles. The OMR is also based on the harmonized outcome measures produced through the Outcome Measures Framework harmonization project, conducted by L&M Policy Research and its subcontractors OM1 and Academy Health. In constructing this framework and corresponding data definitions, these organizations consulted with work groups comprising registry sponsors/developers, policymakers, clinicians, informaticists, patients/caregivers, and representatives from industry, health systems, federal agencies, and relevant non-governmental organizations.

9. Payments/Gifts to Respondents

Participation in the OMR is voluntary. As such, there is no payment or remuneration offered to users for entering an outcome measure in the OMR system.

10. Assurance of Confidentiality

Individuals and organizations are to be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c), which requires that information that is obtained in the course of AHRQ-supported activities and that identifies individuals or establishments be used only for the purpose for which it was supplied. Information that is obtained in the course of AHRQ-supported activities and that identifies an individual may be published or released only with the consent of the individual who supplied the information or is described in it.

When creating an OMR (or RoPR) account, users are required to enter an email address associated with the account. This information is mandatory and is not made public. It is

only used for administrative purposes such as communicating information about password updates and resets. First name, last name, and organization fields are optional.

For each measure, the OMR interface collects the e-mail address of the measure record owner. This information is mandatory and is not made public. It is used only for periodic auto-generation of e-mail reminders pertaining to the maintenance of outcome measure records. There is no human administrator that is pulling this information for the purpose of sending out e-mails. Therefore, individuals contributing to the OMR are told the purposes for which this information (e.g., e-mail) is collected, in accordance with the Privacy Act, not to be used, or disclosed for any other purpose than for the OMR. To this effect, a disclaimer statement is clearly stated within the OMR system: *“This email will only be used by OMR and will not be distributed.”*

Registration burden is reduced by clearly indicating that the submission of First Name/Last Name, of the primary contact person purely voluntary, for the purpose of knowledge exchange between the measure steward and concerned members of the public (See Attachment C: Privacy Impact Assessment for The Registry of Patient Registries).

11. Questions of a Sensitive Nature

The OMR does not collect any information of a sensitive nature, or information that can directly identify the respondent, such as a social security number or Medicare/Medicaid number.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondent’s time to contribute to the OMR.

Based on the number of respondents submitting RoPR records in 2016 (65 respondents), it is expected that a similar number of stakeholders (approximately 70 respondents) will provide measure information in the OMR on an annual basis.

All users will complete required fields on the “Measure Profile” form. Some users will also choose to complete the “Sub-Element Profile” form for one or more sub-elements associated with a given measure. Sub-element information is not required. The number of sub-elements for a given measure is expected to vary widely. Many users may not provide sub-element information, while others may include five or more. It is expected that on average, measure stewards will enter information for two sub-elements.

In September 2017, Truven Health Analytics consulted with several stakeholders and used a sample of existing measure definitions to estimate the time required to enter all OMR fields. The sample included measures representing a range of depth and complexity. For example, one measure record contained no sub-element information, only required fields, and short responses to open text fields (e.g., title and description). Another record contained two sub-elements, all optional fields, and longer responses to open text fields.

As a result of the knowledge gained during these processes, it is estimated that it will take users 16 minutes, on average, to manually enter the additional fields added through the self-registration process (an average of 12 minutes to complete the Measure Profile form and 4 minutes to complete two Sub-Element Profile sub-forms). If 70 respondents complete the Measure Profile form and two Sub-Element Profile sub-forms, the estimated annualized burden would be 18.7 hours total.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
OMR Measure Profile / Sub-Element Profile	70	1	16/60	18.7
Total	70	1	16/60	18.7

Exhibit 2 shows the estimated cost burden associated with the respondent’s time to participate in the OMR. The total cost burden to respondents is estimated at an average of \$711.72 annually.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate [†]	Total cost burden
OMR Measure Profile / Sub-Element Profile	70	18.7	\$38.06	\$711.72
Total	70	18.7	\$38.06	\$711.72

* Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29-0000. National Compensation Survey: Occupational Wages in the United States May 2016, “U.S. Department of Labor, Bureau of Labor Statistics.” Available at: <https://www.bls.gov/oes/current/oes290000.htm>

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Costs to the Federal Government

Costs to the federal government are those costs associated with work by AHRQ’s contractor, L&M Policy Research; and L&M’s sub-contractors, Truven Health Analytics, an IBM Company, and OM1, to develop a prototype of the OMR and implement the system within the existing RoPR site. Over a two-year period, the total amount allocated for these tasks is \$1,488,029.00. As such, the estimated annualized cost to the federal government is \$744,014.50.

Per exhibit 3, the Federal Government Personnel Cost (at approximately 5%, or 104 hours, of an FTE Project Officer, GS 15, Step 5) is estimated at \$7,258.10 on an annual basis.

Exhibit 3. Federal Government Personnel Cost

Activity	Federal Personnel*	Annual Rate	Estimated Hours	Annual Cost
Project Oversight	Project Officer, GS 15, Step 5	\$145,162	104	\$7,258.10
Total				\$7,258.10

Annual salaries based on 2016 OPM Pay Schedule for Washington/DC area:
<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/20152016/DCB.pdf>

15. Changes in Hour Burden

The OMR is a new data collection instrument.

16. Time Schedule, Publication, and Analysis Plans

There are no plans to publish or analyze the information collected in the OMR at this time.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Federal Register Notice

Attachment B: OMR Record (Data Collection Instrument)

Attachment C: Privacy Impact Assessment