BILLING CODE 4160-90-M

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 "Outcome Measure Repository (OMR)."

DATES: Comments on this notice must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION]**.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at 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 emails at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Outcome Measure Repository

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites public comment on this proposed information collection. In accordance with the agency's mission,

AHRQ developed the Outcome Measure Repository (OMR), a web-based database with the purpose of providing a readily available public resource that includes definitions of outcome measures associated with patient registries. The information being collected in each OMR record will be visible to the public and readily available for public use.

This effort is in alignment the AHRQ Registry of Patient Registries (RoPR), which provides a centralized point of collection for information about all patient registries in the United States. The RoPR furthers AHRQ's goals to enhance the description of the quality, appropriateness, and effectiveness of health services, and patient registries in particular, in a more readily available, central location by enhancing patient registry information, extracted from ClinicalTrials.gov or modeled based on the ClinicalTrials.gov data elements.

The development of the OMR continues these efforts, and 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; and

3) Facilitate the identification of potential areas of harmonization.

The OMR 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 patient registry in RoPR. 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).

This study is being conducted 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).

Method of Collection

To achieve the three objectives of this project, information on outcome measures and related sub-elements from measure stewards who populate the OMR database system will be collected. 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.

Estimated Annual Respondent Burden

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 may also choose to complete the "Sub-Element Profile" form for one or more sub-elements associated with a given measure although this 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 enter manually 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

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical

utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

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