Committee on Economic Statistics

Federal Data Collection Comment Opportunity for AEA Members

Outcome Measures Repository
Agency for Healthcare Research and Quality

Comments Due March 30, 2018

The Agency for Healthcare Research and Quality (AHRQ) plans to ask OMB to approve 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.

The OMR 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.

Background: "Outcome Measures Framework: Literature Review, Findings and Implications"

AEA members are encouraged to:

- provide opinions on the value of OMR for economic research;
- comment on the data collection instruments and methods; and
- suggest changes that would enhance data quality, value, and accessibility and lower respondent burden and federal cost.

Federal Register notice: January 29, 2018 (includes detailed information on data collection and instructions for submitting comments)

- Draft OMR data collection website (attached)
- Draft Supporting Statement (attached)
- Due date for comments: March 30, 2018
- Point of contact: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, doris.lefkowitz@AHRQ.hhs.gov

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Information on Information Collection Request (ICR) Process:

- By law, each data collection carried out by a federal agency must be cleared by OMB. Through this *Federal Register* notice, AHRQ is announcing that it intends to submit a

request to OMB for clearance to construct the OMR and offers the public a 60-day opportunity to submit comments.

- After the close of the 60-day comment period, AHRQ will prepare and submit its request to OMB. That request will summarize and respond to each of the public comments it received.

Guidance to AEA Members on Preparing Comments:

- Can comment on any aspect of the proposed data collection. Possible topics, for instance, include needs, uses, methodology, design, cost, schedule, and consultation with data users.
- May frame comments on specific topics in any way, such as:
  - assessments – identifying what you do and do not like and support
  - suggestions – for how AHRQ might proceed in this or future collections
  - requests – for example, for a change in the design of the survey instrument, to be consulted in the future, to carry out research on an alternative approach
  - observations – for example, implications of the sample size for statistical reliability
- May propose that OMB incorporate a request in its "terms of clearance." For instance, you could suggest as a term of clearance that AHRQ research the efficacy of an alternative set of questions and report back to OMB in a year on the results.

Additional AEA Resources:

- A Primer on How to Respond to Calls for Comment on Federal Data Collections
- After reviewing materials, you may provide your observations, critiques, and requests to AEAStat staff Andrew Reamer at areamer@gwu.edu and he will organize them into a draft letter for your review. Prof. Reamer is experienced in crafting comment letters for impact.

SUPPORTING STATEMENT

Part A

American Recovery and Reinvestment Act
"Registry of Patient Registries"
Contract No. HHSA290201400004C

Version: ~~20~~ ~~4~~12 ~~October~~ January ~~2017~~2018

Agency ~~of~~ for Healthcare Research and Quality (AHRQ)

Table of Contents

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 ~~Registry of Patient Registries (~~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~~, which will achieve all of the above goals~~.

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, ~~quality, effectiveness, efficiency, appropriateness and value of healthcare services~~ and with respect to health statistics and database development~~quality measurement and improvement~~. 42 U.S.C. 299a(a)(~~1~~3) and (~~2~~8).

2. Purpose and Use of Information

The purpose ~~and the use~~ 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

Comment [MK1]: Needs to be updated with dates when we know this information.

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on Page XXXX of Federal Register, XXXXXX, XX, 2017 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 AcademyHealth. 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 RoPR 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 PII, 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.

The SORN published with the 60-Day Federal Register, on XXXXX XX, ~~2017~~2018, is as follows:

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: *"Developing an Outcome Measures Repository for the Registry of Patient Registries."* 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 XXXXX XX, 2017.

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 email at *doris.lefkowitz@AHRQ.hhs.gov*.

Federal Register / Vol. 80, No. 182 / XXXXXXXXXXXXX **56990**

Comment [BE(2]: I don't believe this text is needed here. I'll place an example of the text that was used with RoPR.

For each registry, the RoPR interface collects the e-mail address of the RoPR 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 RoPR patient registry data. There is no human administrator that is pulling this information for the purpose of sending out e-mails. Therefore, individuals registering patient registries via the RoPR 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 RoPR. To this effect, a disclaimer statement is clearly stated within the RoPR system: *"This email will only be used by RoPR and will not be distributed."*

The RoPR record owner has the option to select "Do not contact" on the RoPR. This selected option does not exempt the RoPR user from having to complete these "mandatory" fields: *Reasons for being contacted; Organization; E-mail and Phone.*

PII (First/Last Name) and Title fields are non - mandatory entries, which are indicated as optional fields as a user completes the RoPR profile. This information is available publically for intended uses as identified by the accompanying categories detailing the sponsor's reasons for being contacted. In this case, the Privacy Act is not applicable, however the collection of PII is deemed necessary for collection on the RoPR, for the following reasons:

Comment [BE(3]: This is the example. I'll also send the last RoPR SS Part A.

The RoPR is an information repository which connects patient registries with individuals interested in learning more about them and how they advance healthcare. Many patient registries find it mutually beneficial to provide primary contact information to facilitate dialogue between them and interested parties. Patient registries comprise a highly specialized field. Only a subset of the general public would be interested in pursuing dialogue with a particular patient registry, motivated by interest in specific medical conditions being examined. Extra security measures have been taken so that PII is not searchable on the RoPR, in the live or administrative environments.

Registration burden is reduced by clearly indicating that the submission of PII, First Name/Last Name, of the primary contact person purely voluntary, for the purpose of knowledge exchange between the patient registry 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.

~~In 2016, 65 respondents manually entered a new RoPR record. It is expected that more than 75% of patient registries are research-focused and will continue to use the original ClinicalTrials.gov pathway described above. Thus, it is estimated that once the self-registration pathway is available, approximately 65 respondents will enter RoPR records through the ClinicalTrials.gov link annually, and an additional 16 respondents (roughly 25% of 65), representing non-research registries, will enter RoPR records through the new self-registration pathway.~~

Based on the number of respondents submitting RoPR records in 2016 (65 respondents), i~~I~~t 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~~4~~ 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~~2~~ minutes to complete ~~each~~ 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 ~~18.723.3~~ 18.7 hours total.

Comment [MA4]: Please see email description. 18.7 hours total should be retained.

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	~~12~~16/60	~~14.0~~18.7
~~OMR Sub-Element Profile~~	~~70~~	~~2~~	~~4/60~~	~~4.7~~9.3

Formatted Table

Comment [MA5]: The paragraph above specifies that it should be 1 Measure Profile (@ 12 mins) plus 2 Sub-Element Profiles (@ 2 mins each), totaling 16 minutes per individual respondent.

Total	70	~~2~~1	16/60~~14/60~~	18.7~~18.723.3~~

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 $~~620.38~~711.72annually.

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	~~14.0~~18.7	$38.06	$~~532.84~~711.72
~~OMR Sub-Element Profile~~	~~70~~	~~4.79~~3	~~$38.06~~	~~$178.88~~353.96
Total	70	~~16.323.~~318.7	$38.06	$~~711.72886.82~~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

Comment [BE(6]: How are you calculating this estimate.

Comment [MA7]: This was a mistake.

Formatted Table

Comment [MA8]: Addition error.

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

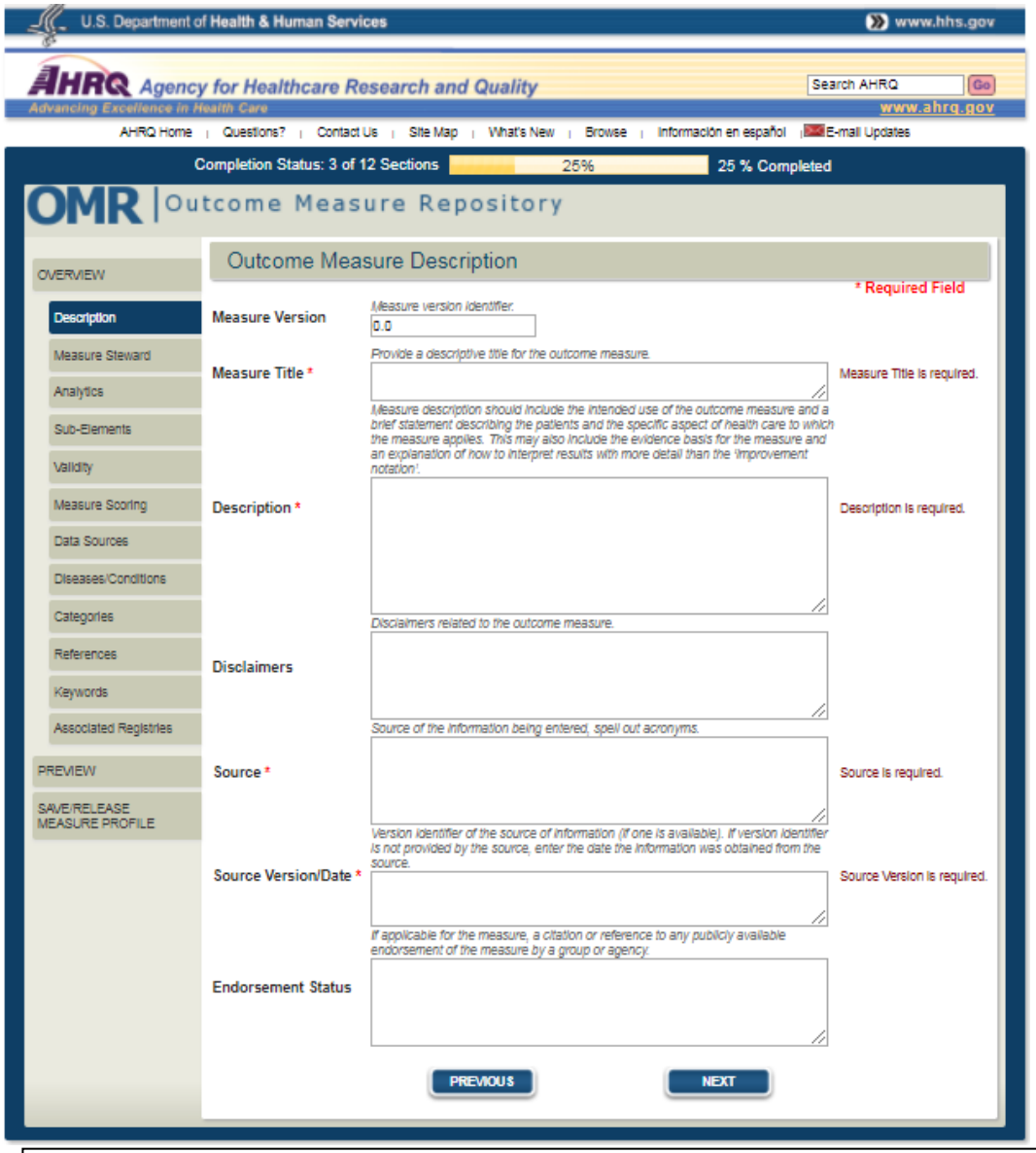
Form Approved
OMB No. 0935-XXXX
Exp. Date XX/XX/20XX

Attachment B: Questionnaires/Data Collection Instruments

The OMR data collection system is a web-based collection mechanism. The screenshots included in this document represent all sections that will be visible to registered users completing a Measure Profile and Sub-Element Profile. The Measure Profile has 12 sections and the Sub-Element Profile has 1 section.

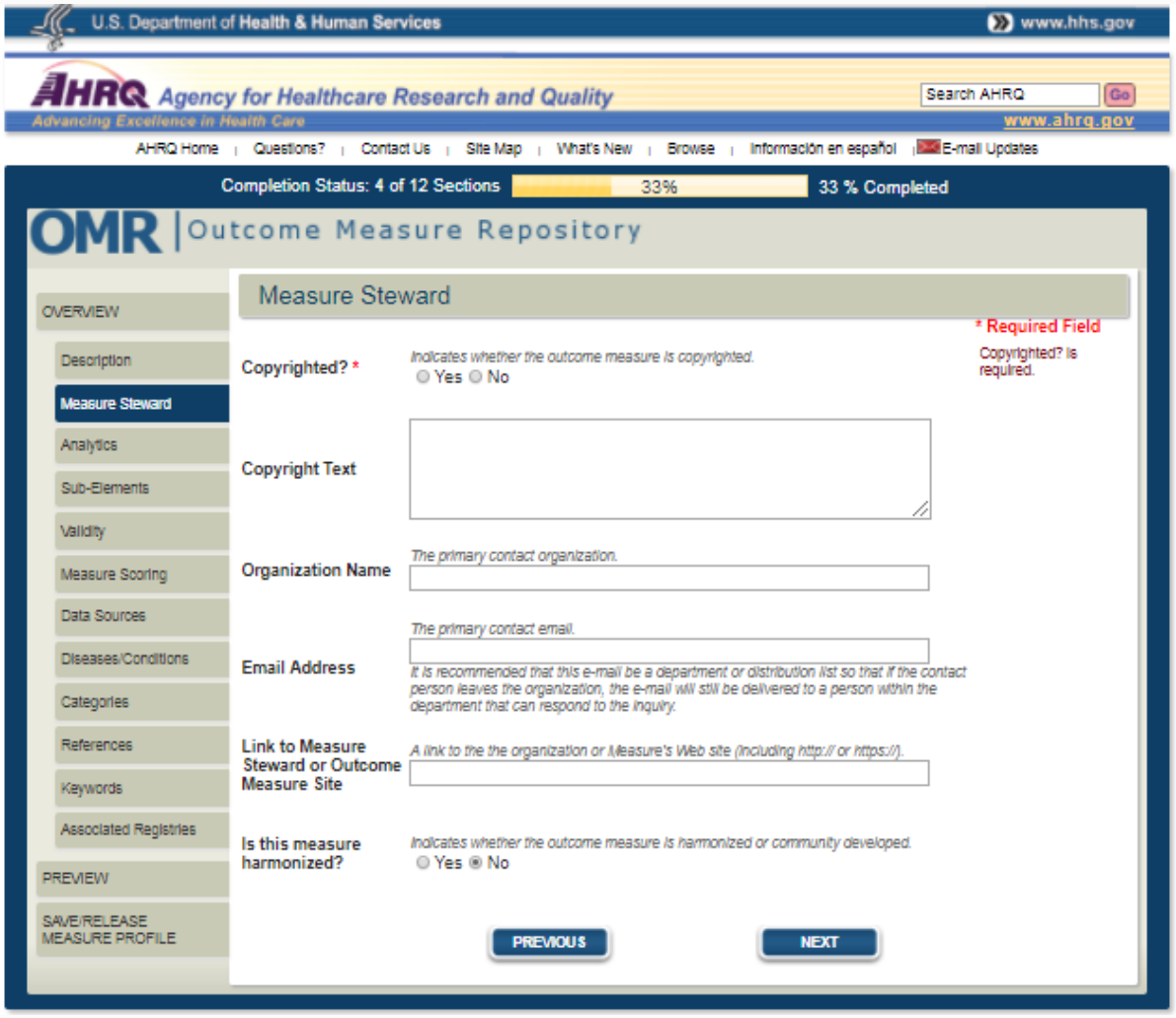
MEASURE PROFILE

1)



Public reporting burden for this collection of information is estimated to average 16 minutes per response, the estimated time required to complete the survey. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer Attention: PRA, Paperwork Reduction Project (0935-XXXX) AHRQ, 5600 Fishers Lane, # 07W41A, Rockville, MD 20857.

2)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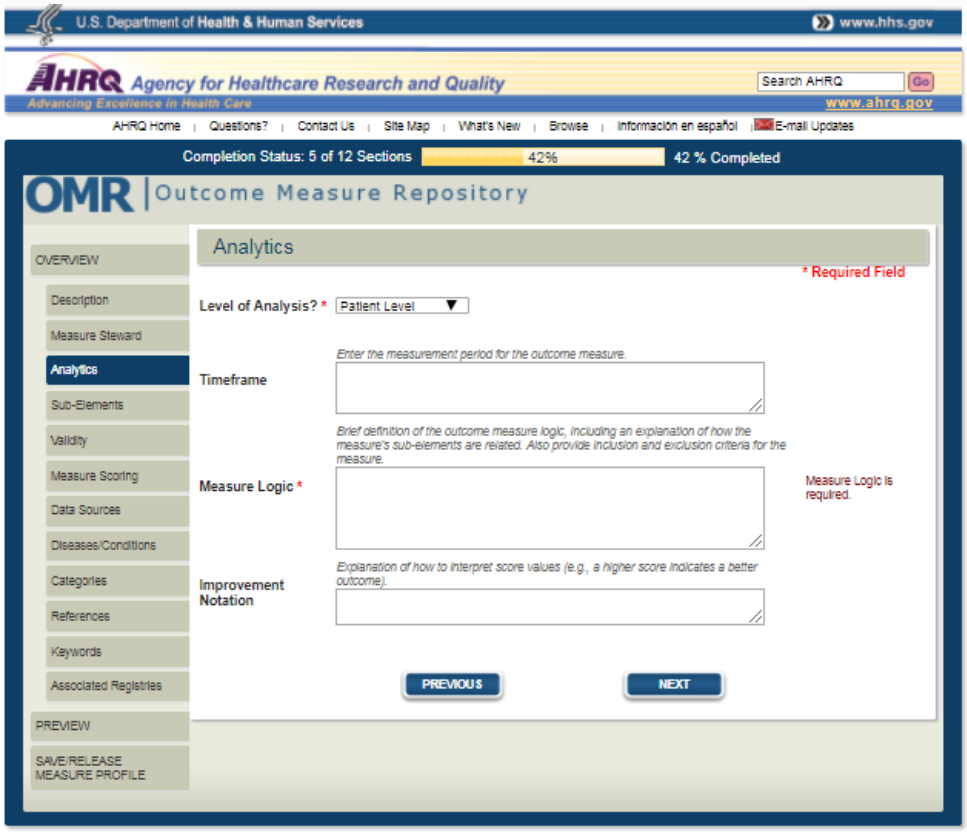
Completion Status: 4 of 12 Sections
33%
33 % Completed
OMR | Outcome Measure Repository
OVERVIEW
Description
Measure Steward
Analytics
Sub-Elements
Validity
Measure Scoring
Data Sources
Diseases/Conditions
Categories
References
Keywords
Associated Registries
PREVIEW
SAVE/RELEASE MEASURE PROFILE
Measure Steward
* Required Field
Copyrighted? *
Indicates whether the outcome measure is copyrighted.
Yes No
Copyrighted? is required.
Copyright Text
Organization Name
The primary contact organization.
Email Address
The primary contact email.
It is recommended that this e-mail be a department or distribution list so that if the contact person leaves the organization, the e-mail will still be delivered to a person within the department that can respond to the inquiry.
Link to Measure Steward or Outcome Measure Site
A link to the the organization or Measure's Web site (including http:// or https://).
Is this measure harmonized?
Indicates whether the outcome measure is harmonized or community developed.
Yes No
PREVIOUS
NEXT

3)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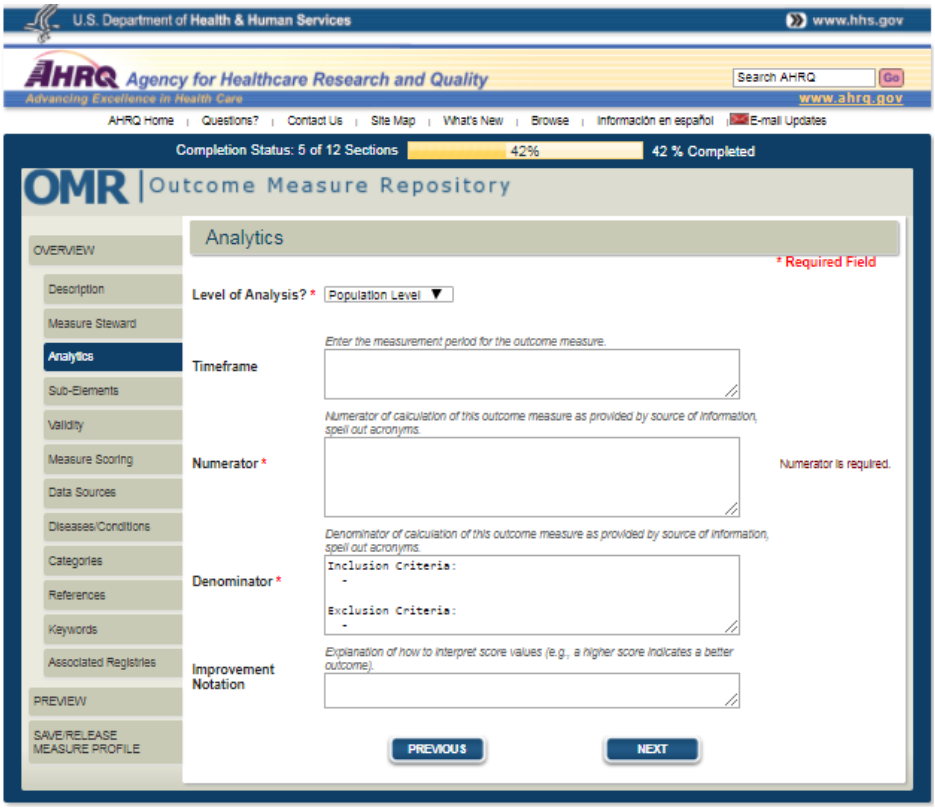
Completion Status: 5 of 12 Sections
42%
42 % Completed
OMR | Outcome Measure Repository
OVERVIEW
Description
Measure Steward
Analytics
Sub-Elements
Validity
Measure Scoring
Data Sources
Diseases/Conditions
Categories
References
Keywords
Associated Registries
PREVIEW
SAVE/RELEASE MEASURE PROFILE
Analytics
* Required Field
Level of Analysis? * Patient Level
Timeframe
Enter the measurement period for the outcome measure.
Measure Logic *
Brief definition of the outcome measure logic, including an explanation of how the measure's sub-elements are related. Also provide inclusion and exclusion criteria for the measure.
Measure Logic is required.
Improvement Notation
Explanation of how to interpret score values (e.g., a higher score indicates a better outcome).
PREVIOUS
NEXT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Completion Status: 5 of 12 Sections
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OMR | Outcome Measure Repository
OVERVIEW
Description
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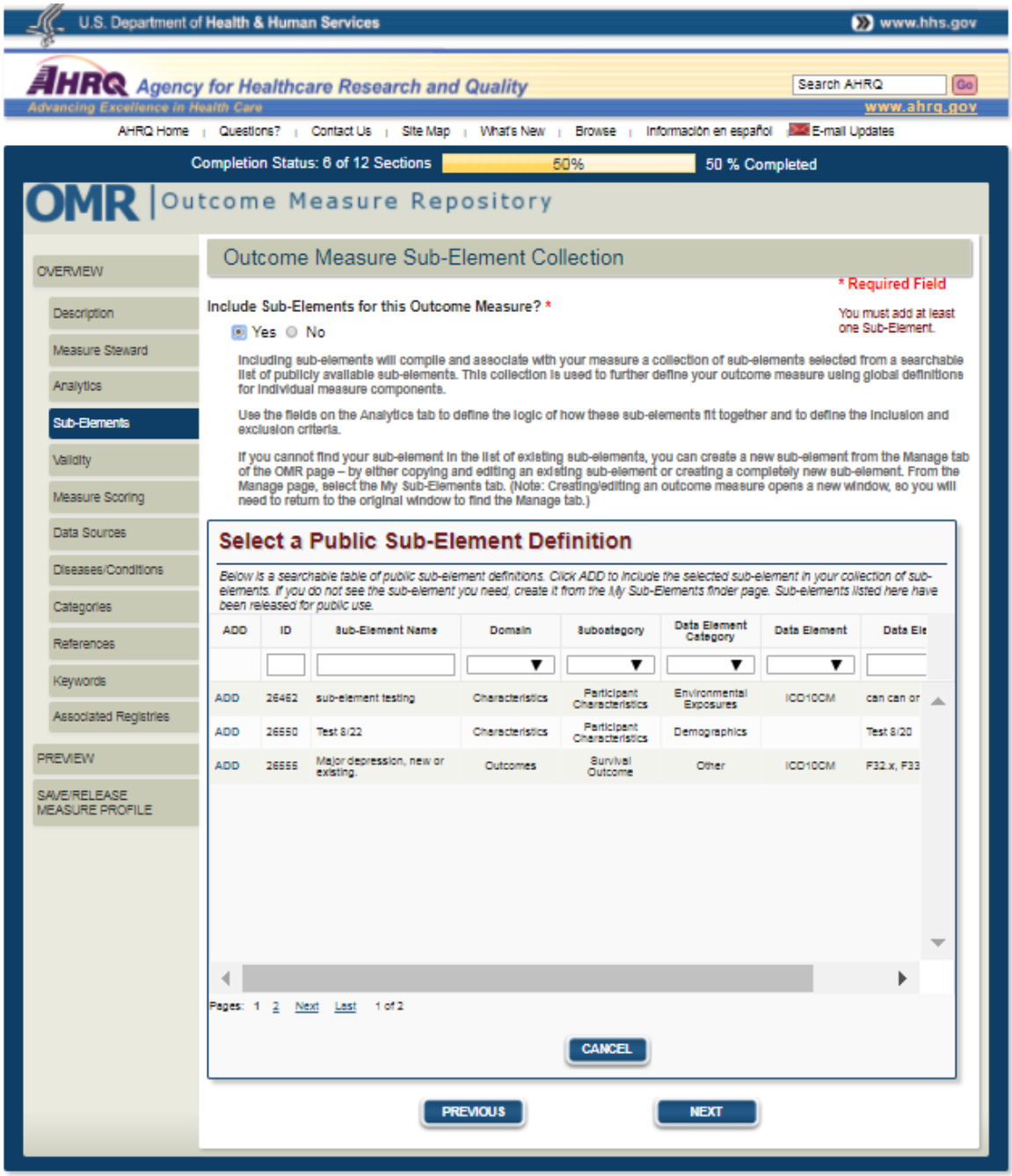
Analytics
Sub-Elements
Validity
Measure Scoring
Data Sources
Diseases/Conditions
Categories
References
Keywords
Associated Registries
PREVIEW
SAVE/RELEASE MEASURE PROFILE
Analytics
* Required Field
Level of Analysis? * Population Level
Timeframe
Enter the measurement period for the outcome measure.
Numerator *
Numerator of calculation of this outcome measure as provided by source of information, spell out acronyms.
Numerator is required.
Denominator *
Denominator of calculation of this outcome measure as provided by source of information, spell out acronyms.
Inclusion Criteria:
-
Exclusion Criteria:
-
Improvement Notation
Explanation of how to interpret score values (e.g., a higher score indicates a better outcome).
PREVIOUS
NEXT

4)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50 % Completed
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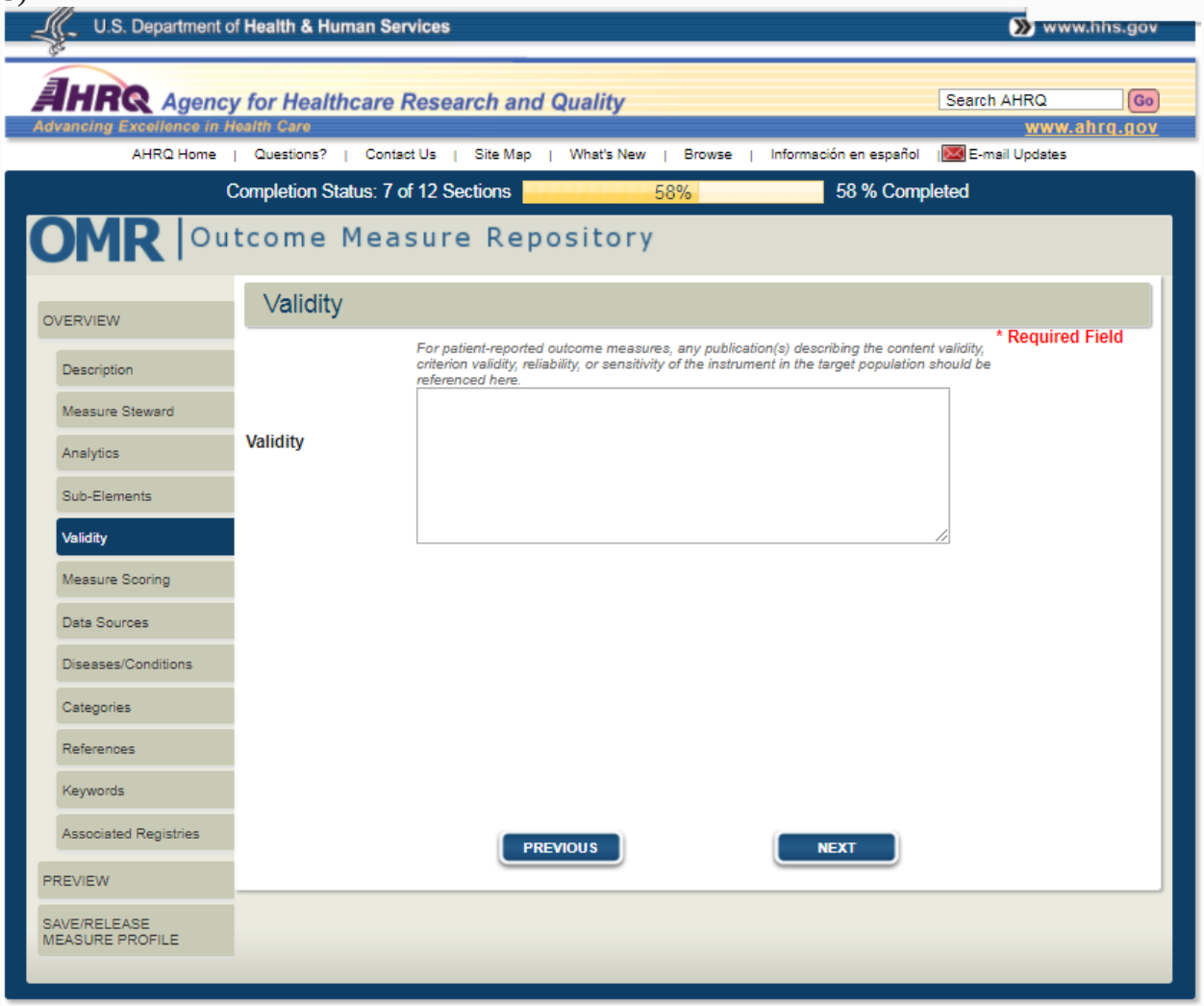
Validity
Measure Scoring
Data Sources
Diseases/Conditions
Categories
References
Keywords
Associated Registries
PREVIEW
SAVE/RELEASE MEASURE PROFILE
Outcome Measure Sub-Element Collection
* Required Field
Include Sub-Elements for this Outcome Measure? *
You must add at least one Sub-Element.
Yes
No
Including sub-elements will compile and associate with your measure a collection of sub-elements selected from a searchable list of publicly available sub-elements. This collection is used to further define your outcome measure using global definitions for individual measure components.
Use the fields on the Analytics tab to define the logic of how these sub-elements fit together and to define the inclusion and exclusion criteria.
If you cannot find your sub-element in the list of existing sub-elements, you can create a new sub-element from the Manage tab of the OMR page – by either copying and editing an existing sub-element or creating a completely new sub-element. From the Manage page, select the My Sub-Elements tab. (Note: Creating/editing an outcome measure opens a new window, so you will need to return to the original window to find the Manage tab.)
Select a Public Sub-Element Definition
Below is a searchable table of public sub-element definitions. Click ADD to include the selected sub-element in your collection of sub-elements. If you do not see the sub-element you need, create it from the My Sub-Elements finder page. Sub-elements listed here have been released for public use.
ADD
ID
Sub-Element Name
Domain
Subcategory
Data Element Category
Data Element
Data Ele
ADD 26462 sub-element testing Characteristics Participant Characteristics Environmental Exposures ICD10CM can can or
ADD 26550 Test 8/22 Characteristics Participant Characteristics Demographics Test 8/20
ADD 26555 Major depression, new or existing. Outcomes Survival Outcome Other ICD10CM F32.x, F33
Pages: 1 2 Next Last 1 of 2
CANCEL
PREVIOUS
NEXT

5)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Completion Status: 7 of 12 Sections
58%
58 % Completed
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Data Sources
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Keywords
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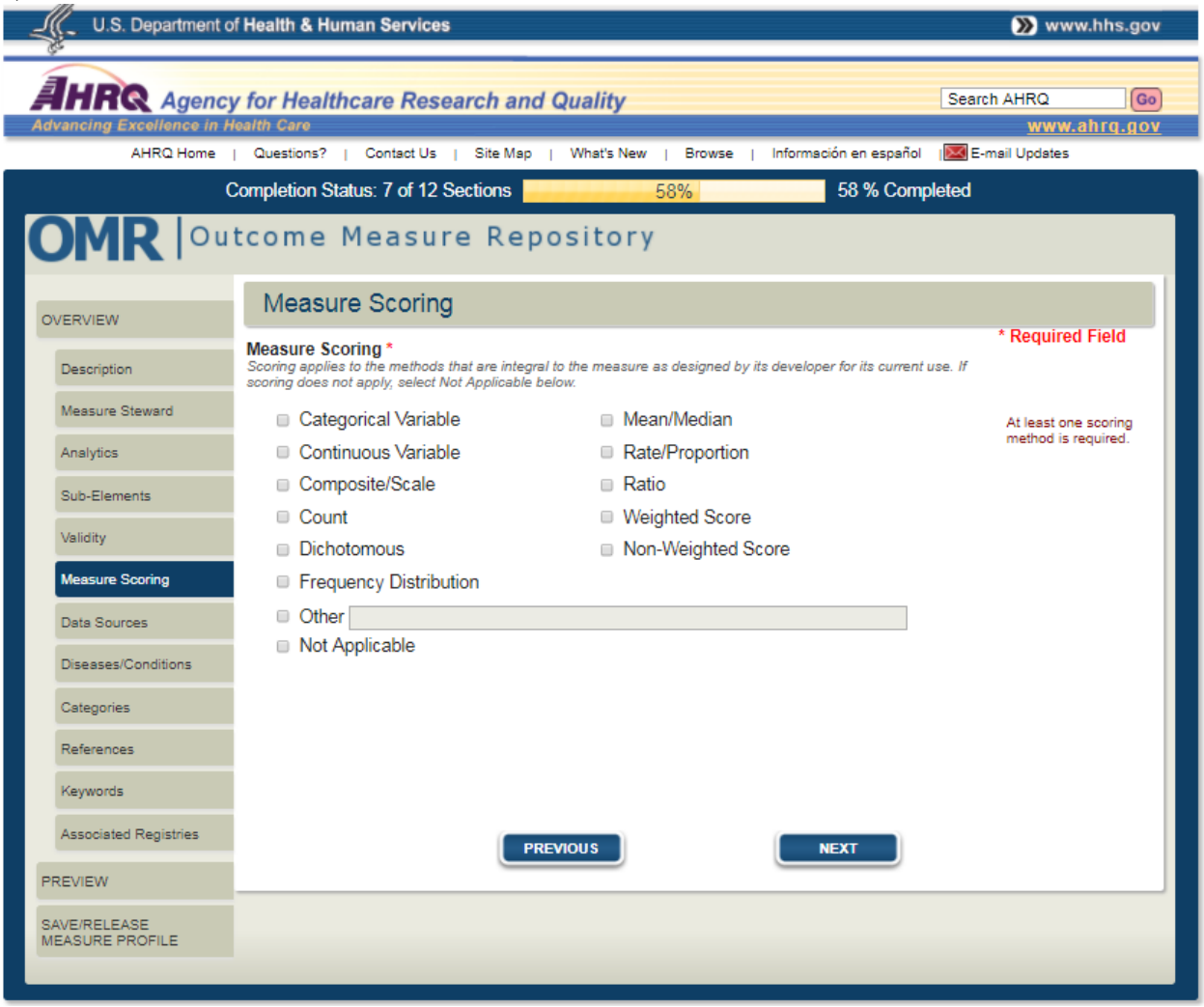
PREVIEW
SAVE/RELEASE MEASURE PROFILE
Validity
* Required Field
For patient-reported outcome measures, any publication(s) describing the content validity, criterion validity, reliability, or sensitivity of the instrument in the target population should be referenced here.
Validity
PREVIOUS
NEXT

6)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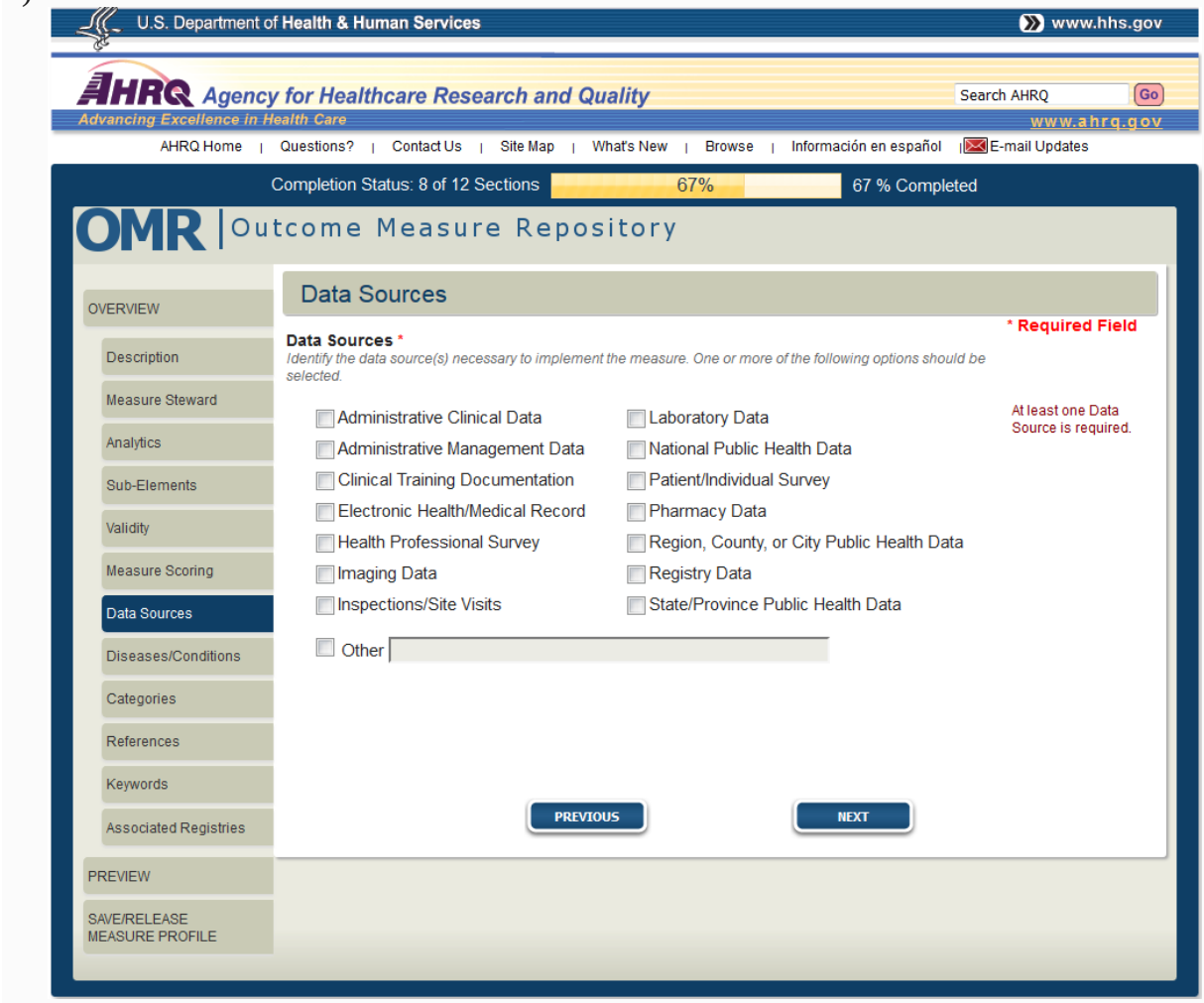
Measure Scoring
* Required Field
Measure Scoring *
Scoring applies to the methods that are integral to the measure as designed by its developer for its current use. If scoring does not apply, select Not Applicable below.
Categorical Variable
Continuous Variable
Composite/Scale
Count
Dichotomous
Frequency Distribution
Other
Not Applicable
Mean/Median
Rate/Proportion
Ratio
Weighted Score
Non-Weighted Score
At least one scoring method is required.
PREVIOUS
NEXT

7)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67%
67 % Completed
OMR | Outcome Measure Repository
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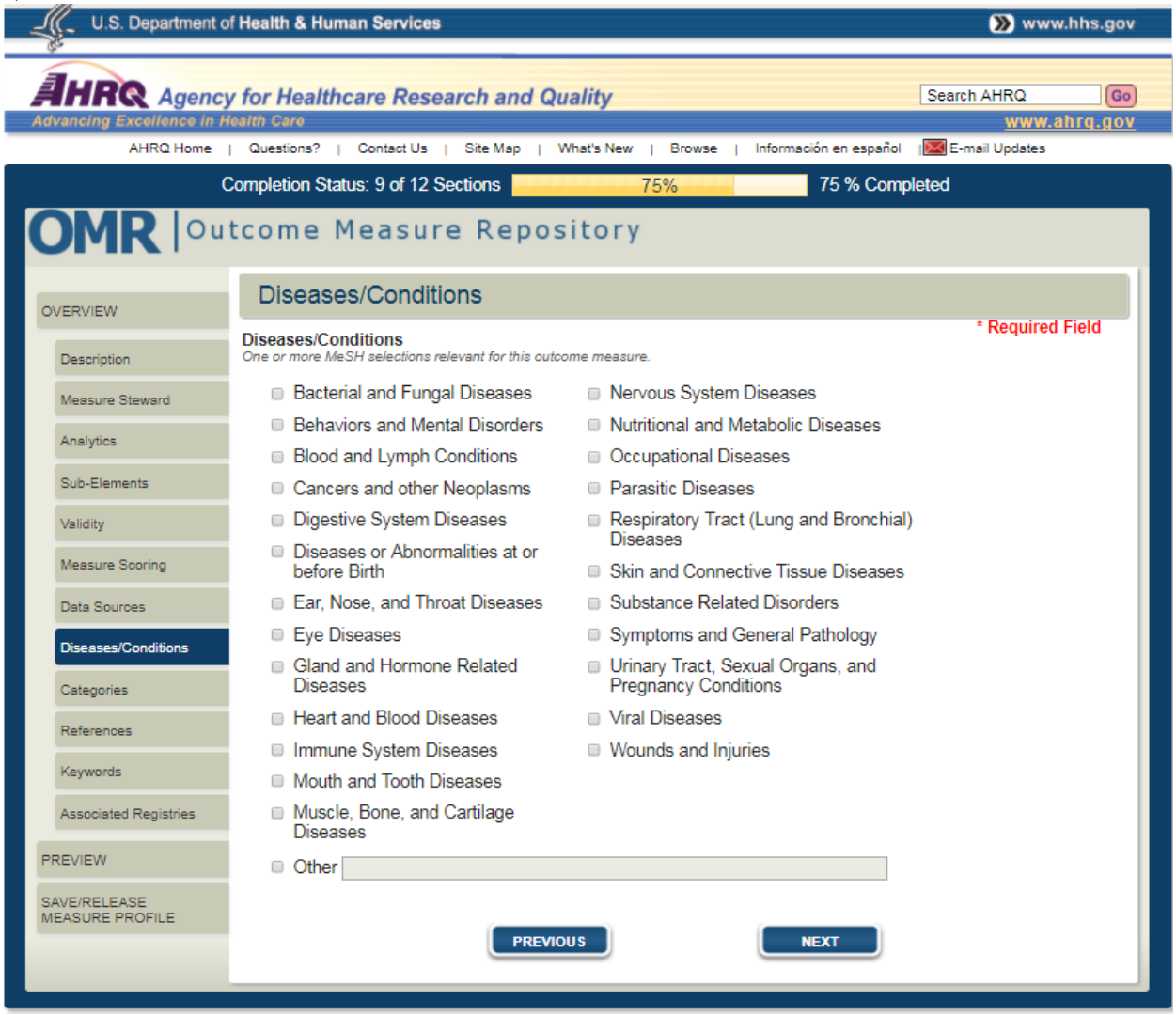
SAVE/RELEASE MEASURE PROFILE
Data Sources
* Required Field
Data Sources *
Identify the data source(s) necessary to implement the measure. One or more of the following options should be selected.
Administrative Clinical Data
Administrative Management Data
Clinical Training Documentation
Electronic Health/Medical Record
Health Professional Survey
Imaging Data
Inspections/Site Visits
Laboratory Data
National Public Health Data
Patient/Individual Survey
Pharmacy Data
Region, County, or City Public Health Data
Registry Data
State/Province Public Health Data
Other
At least one Data Source is required.
PREVIOUS
NEXT

8)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75%
75 % Completed
OMR | Outcome Measure Repository
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PREVIEW
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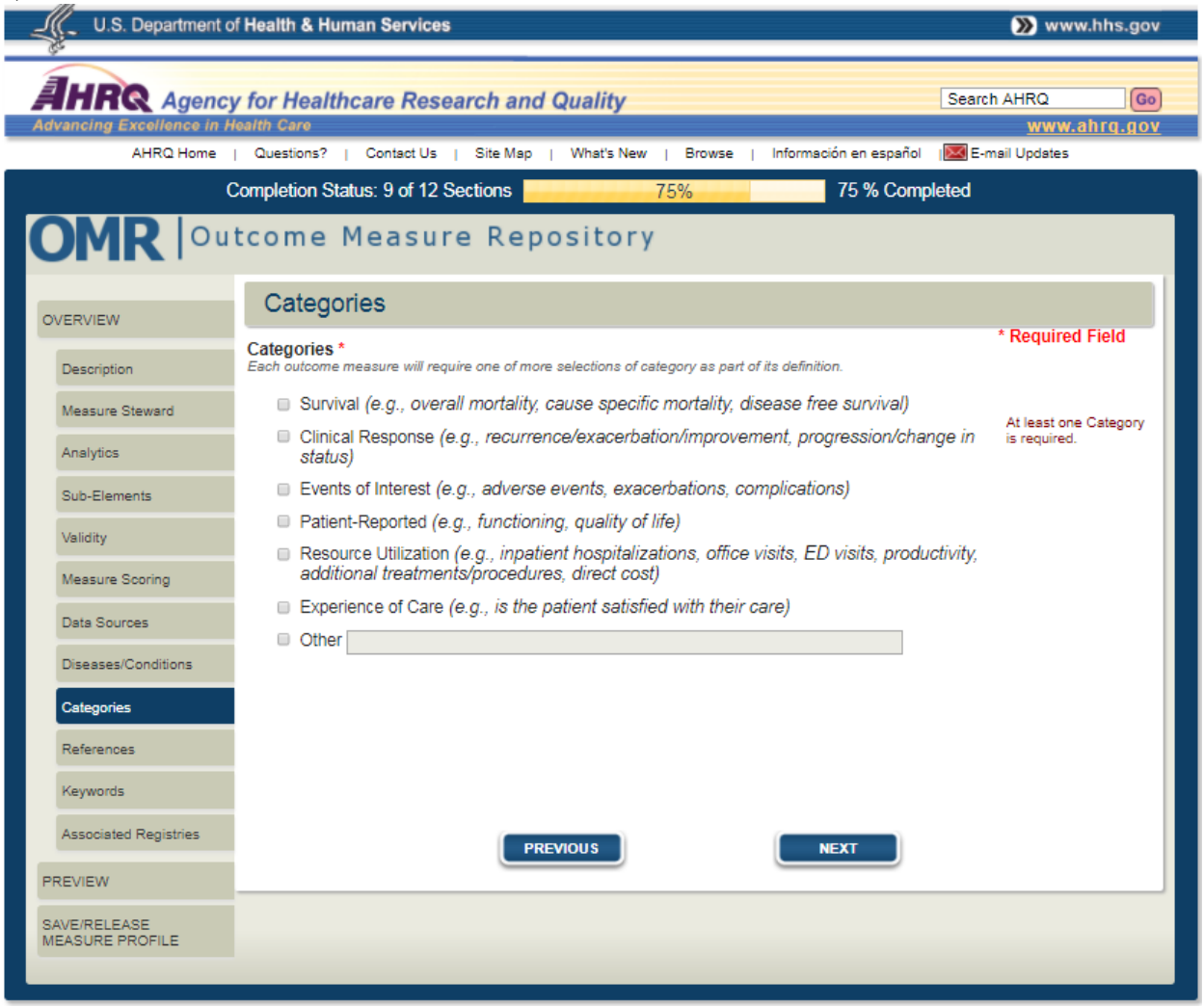
Diseases/Conditions
* Required Field
Diseases/Conditions
One or more MeSH selections relevant for this outcome measure.
Bacterial and Fungal Diseases
Behaviors and Mental Disorders
Blood and Lymph Conditions
Cancers and other Neoplasms
Digestive System Diseases
Diseases or Abnormalities at or before Birth
Ear, Nose, and Throat Diseases
Eye Diseases
Gland and Hormone Related Diseases
Heart and Blood Diseases
Immune System Diseases
Mouth and Tooth Diseases
Muscle, Bone, and Cartilage Diseases
Nervous System Diseases
Nutritional and Metabolic Diseases
Occupational Diseases
Parasitic Diseases
Respiratory Tract (Lung and Bronchial) Diseases
Skin and Connective Tissue Diseases
Substance Related Disorders
Symptoms and General Pathology
Urinary Tract, Sexual Organs, and Pregnancy Conditions
Viral Diseases
Wounds and Injuries
Other
PREVIOUS
NEXT

9)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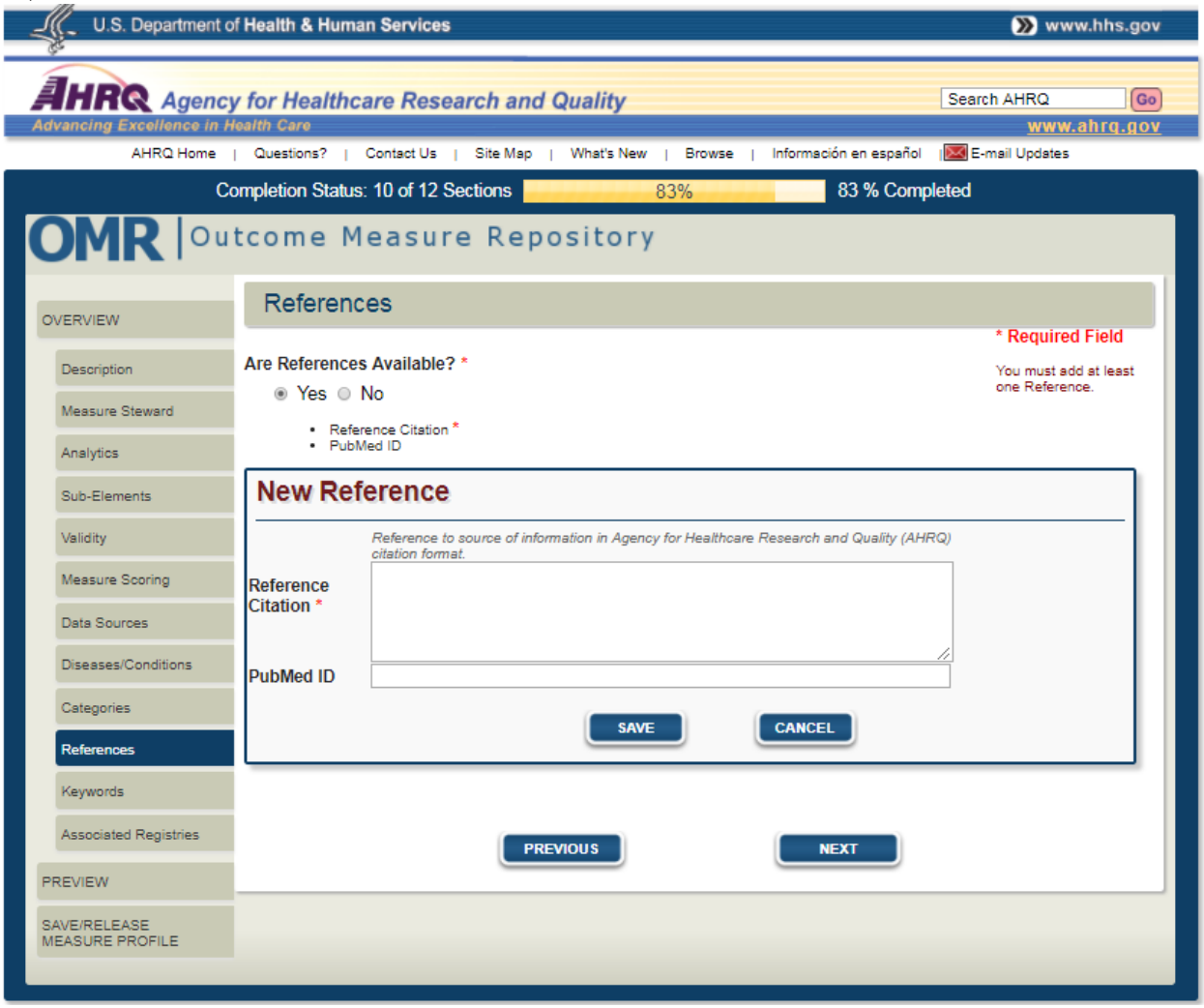
Categories
* Required Field
Categories *
Each outcome measure will require one of more selections of category as part of its definition.
Survival (e.g., overall mortality, cause specific mortality, disease free survival)
Clinical Response (e.g., recurrence/exacerbation/improvement, progression/change in status)
Events of Interest (e.g., adverse events, exacerbations, complications)
Patient-Reported (e.g., functioning, quality of life)
Resource Utilization (e.g., inpatient hospitalizations, office visits, ED visits, productivity, additional treatments/procedures, direct cost)
Experience of Care (e.g., is the patient satisfied with their care)
Other
At least one Category is required.
PREVIOUS
NEXT

10)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83%
83 % Completed
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PREVIEW
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References
* Required Field
Are References Available? *
Yes
No
You must add at least one Reference.
Reference Citation *
PubMed ID
New Reference
Reference to source of information in Agency for Healthcare Research and Quality (AHRQ) citation format.
Reference Citation *
PubMed ID
SAVE
CANCEL
PREVIOUS
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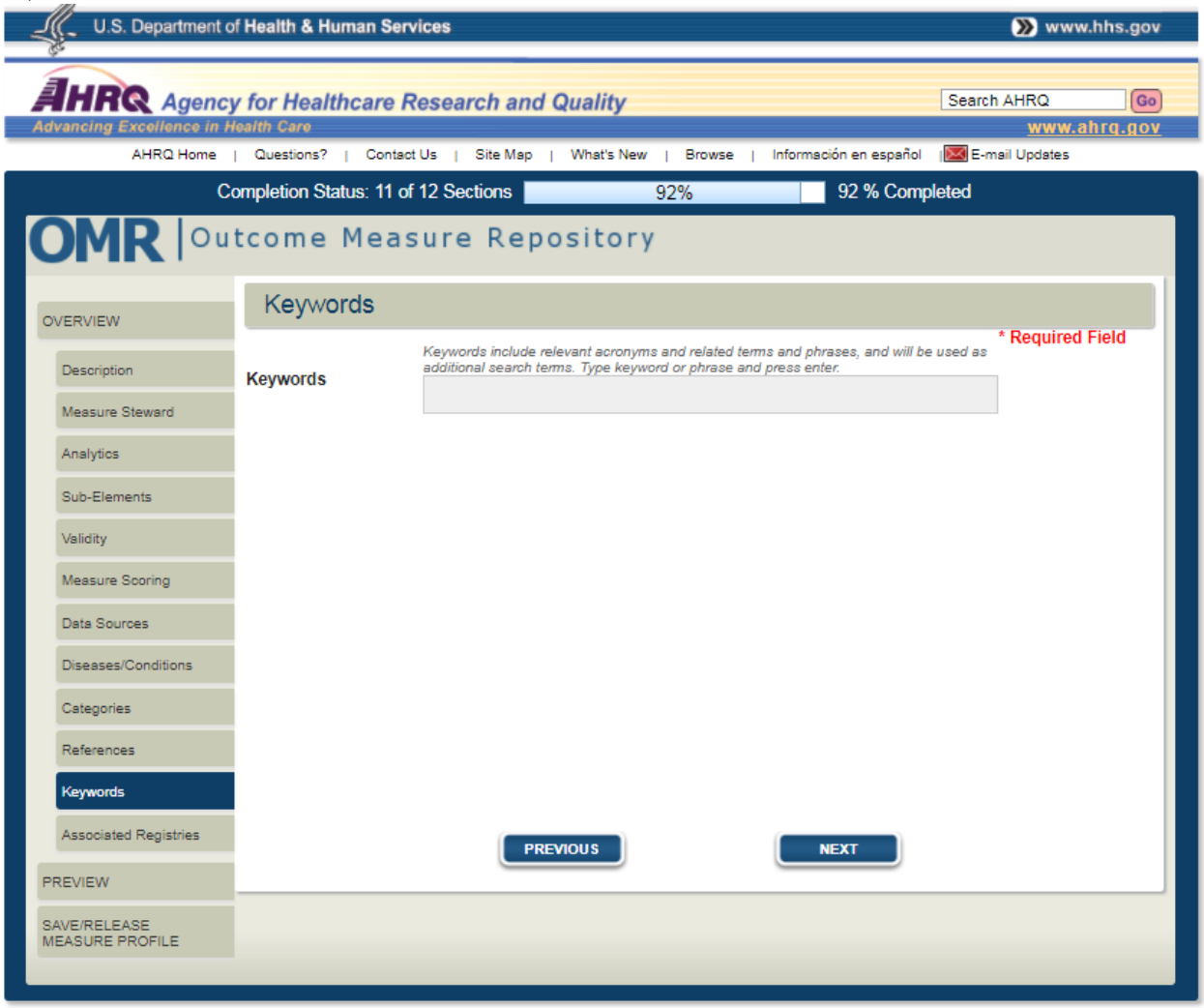
11)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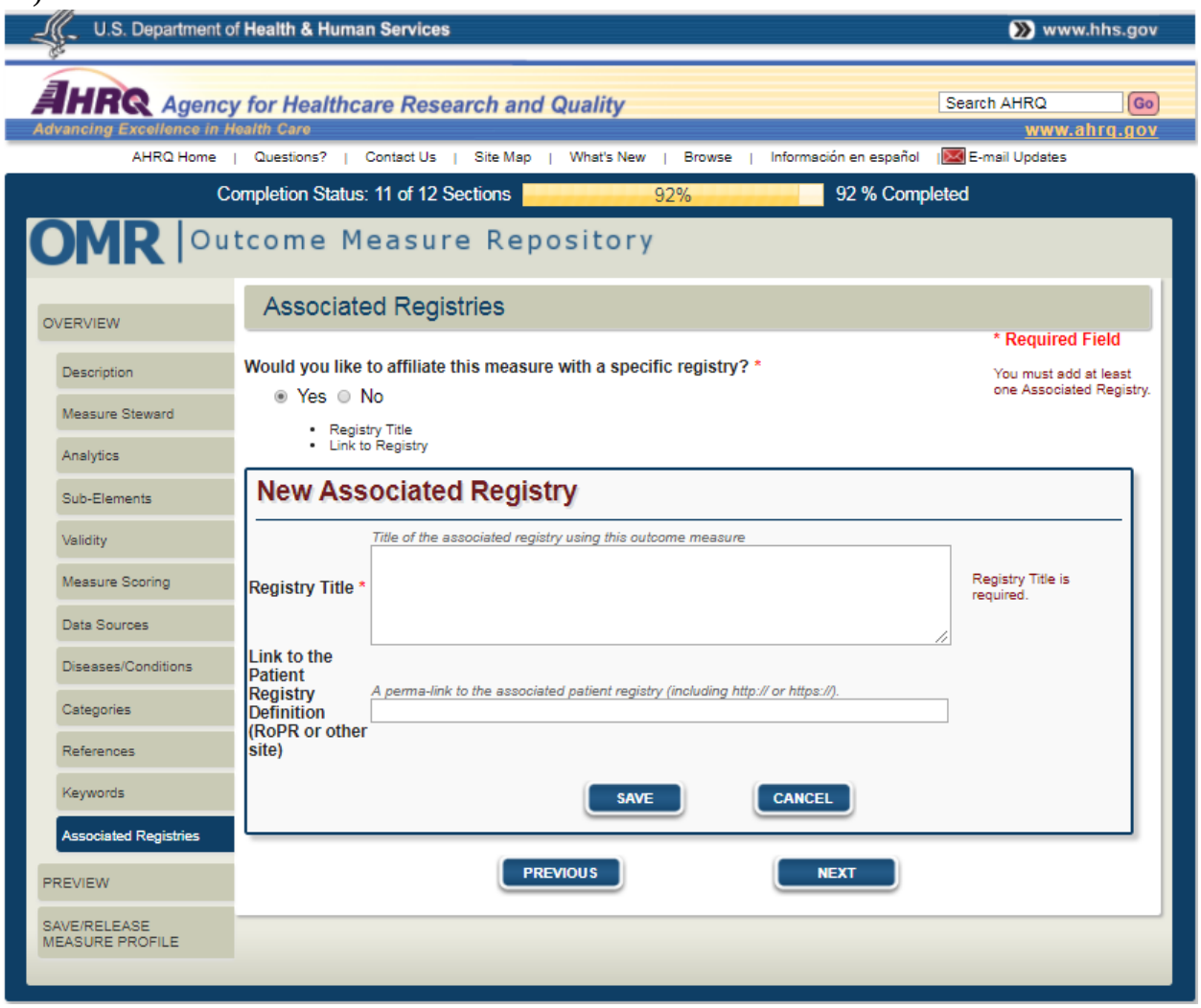
Keywords
* Required Field
Keywords include relevant acronyms and related terms and phrases, and will be used as additional search terms. Type keyword or phrase and press enter.
Keywords
PREVIOUS
NEXT

12)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Associated Registries
* Required Field
Would you like to affiliate this measure with a specific registry? *
Yes
No
You must add at least one Associated Registry.
Registry Title
Link to Registry
New Associated Registry
Title of the associated registry using this outcome measure
Registry Title *
Registry Title is required.
Link to the Patient Registry Definition (RoPR or other site)
A perma-link to the associated patient registry (including http:// or https://).
SAVE
CANCEL
PREVIOUS
NEXT

SUB-ELEMENT PROFILE

1)