REQUEST FOR PROPOSAL (RFP)

DATA VALIDATION OF ANNUAL PHARMACY PERFORMANCE MEASURES

URAC

1220 L STREET NW SUITE 400
WASHINGTON, DC 2005

RFP DATE

November 20, 2017

CLOSING DATE

December 15, 2017

TABLE OF CONTENTS

1. SUMMARY AND BACKGROUND

URAC, an independent, nonprofit organization, is well-known as a leader in promoting health care quality through its accreditation, measurement, and education programs. URAC offers a wide range of quality benchmarking programs and services that keep pace with the rapid changes in the health care system, and provide a symbol of excellence for organizations to validate their commitment to quality and accountability.

URAC is currently accepting proposals to establish a universe of external, independent third-party measure data validators that individual organizations will contract with directly on an annual basis to perform validation services of measures result submissions.

The purpose of this Request for Proposal (RFP) is to solicit proposals from independent, third party validators experienced in: data validation in the electronic and in-person review of pharmaceutical management data systems and associated processes, procedures, mappings, etc.; conduct a fair and extensive evaluation based on criteria listed herein, and select the vendor(s) who provide an informed, efficient response regarding operational and technical qualifications.

URAC Mission

To promote continuous improvement in the quality and efficiency of health care management through processes of accreditation, measurement, and education.

URAC History

In the late 1980's concerns grew over the lack of uniform standards for utilization review (UR) services. UR is the process where organizations determine whether health care is medically necessary for a patient or an insured individual. As a result, URAC's first mission was to improve the quality and accountability of health care organizations using UR programs. In later years, URAC's mission expanded to cover a larger range of service functions found in various health care settings including the accreditation of integrated systems such as health plans to smaller organizations offering specialty services. Now, after 25 years of operation, URAC has over 25 accreditation and certification programs.

From inception, the founders of URAC recognized that an accreditation organization would not be accepted by regulators, health care providers and consumers if controlled by industry interests. To avoid this, several operating principles were incorporated into URAC's structure and bylaws. First, URAC was set up as an organization independent of any particular stakeholder group. Second, the governing Board of Directors was established with representatives from all affected constituencies: consumers, providers, employers, regulators and industry experts.

URAC is one of the fastest growing health care accreditation agencies in the world. URAC will continue to develop new standards for the health care industry and revise existing ones to promote national standards and to ensure that all stakeholders, including consumers and providers, are protected.

2. PROPOSAL GUIDELINES

All proposals must be signed by an official agent or representative of the company submitting the proposal.

If the organization submitting a proposal must outsource or contract any work to meet the requirements contained herein, this must be clearly stated in the proposal. Additionally, all costs included in proposals must be all-inclusive to include any outsourced or contracted work. Any proposals which call for outsourcing or contracting work must include a name and description of the organizations being contracted.

Typical pricing or a pricing structure must include an explanation of all fees and costs proposed for URAC clients.

Contract terms and conditions will be negotiated upon selection of the winning bidder for this RFP. All contractual terms and conditions will be subject to review by URAC's Legal Department. (A sample contract will be provided upon request).

3. PROJECT PURPOSE AND DESCRIPTION

Background

As mentioned previously, URAC currently offers over 25 accreditation programs. Of these, ten (10) contain performance measures that accredited organizations must report on an annual basis to URAC. Measures that either reside in the public domain or for which permission for use is granted to URAC by the measure steward are selected by URAC on an annual basis for organizational reporting under their accreditation(s). Those measures are then classified as Mandatory [M] or Exploratory [E], based on the prevalence of the measure's use and the validity of measurement criteria. Organizations are required to submit all Mandatory measures, pursuant to the RPT-1 standard within the organization's accreditation program, wherein the standard is the unit by which URAC rates accreditation compliance. The RPT-1 standard has a mandatory compliance rating; therefore, failure to submit mandatory measures on an annual basis adversely affects an organization's accreditation status. Exploratory measures are not required for annual reporting, per the "Leading Indicator" compliance rating of the associated RPT-2 standard.

Previously relying solely on the integrity of the submitting organization, URAC is now engaged in a phase-in approach to adopting a greater degree of rigor in reporting by

validation through an external audit. Each phase has a duration of at least 1 year or more. Performance measurement phases include:

- **Phase 1:** Performance measures are reported to URAC on the specified time frequency and are used by the organization for internal performance improvement and, if desired, reporting to customers.
- **Phase 2:** Mandatory performance measures become subject to an external data validation and verification process. During this phase, performance measure results become publicly available as aggregated, de-identified reports.
- **Phase 3:** Organization-specific measure results that have undergone an external data validation and verification process are available publicly on the URAC website.

Currently, data validation is required of pharmacy organizations under five (5) of the accreditation programs. Accredited organizations required to comply with this validation requirement must contract with an approved independent, third-party validator directly for substantiation of rate results, which are submitted to URAC annually between July 1 and September 30.

The external validator is responsible for review of data collection and monitoring processes that enable the organization to report the pharmacy measures. The validation program encompasses multiple components, including document review, review of the organization's submitted rates, mappings, sampling, auxiliary requests (as needed), and a site visit. A final determination of individual measure compliance / non-compliance with measure specifications will be established at the conclusion of the validation.

Following validation process completion, the validator is expected to submit findings to the accredited organization and to URAC in the form of a formal measure data validation report (where applicable), which serves as the basis for validity of the measurement results submitted by the accredited organizations to URAC.

Description of Services

Conduct and report on a multi-faceted program for validation of measure results to be submitted by pharmacy organizations to URAC as part of their ongoing compliance with accreditation standards. (See Appendix A). The validation process consists of, but is not limited to:

- **Source Systems Review:** Each of the accredited organization's source systems contributing data for URAC measure reporting are covered by the validation review. This includes all source platforms where the reported denominator and numerator data originates from. Systems review consists of validation of all processes necessary for measure reporting, including data capture updates / conversions, process times, maintenance, quality assurance / audits, electronic / automation of process, specialized field capture, mapping and system edits.

- **Source Code Review:** All programs, logs, macros, and reference tables used for URAC reporting are submitted to, reviewed by, and approved by the data validator.
- **Data Extract Review:** Review and approval of extraction documentation, including extraction logic, data mapping, aggregation, and other manipulations, must be completed by the validator.
- **Mapping Review:** Organizations may need to map non-standard codes to standard codes in the data extraction process. Validators are required to review documentation for any mappings performed by the accredited organization for URAC measure reporting.
- **Validation Sampling:** URAC requires that validators evaluate the pharmacy organization's reported measures for overall data accuracy, missing information, invalid fields, implausible fields (e.g., range checks), demographic errors, stratification (if applicable), and other data aggregation failures. This is accomplished by performing a source sampling process to reasonably extract and validate a source sample from the pharmacy organization reported measures. Validators must obtain and examine documentation from the primary source system for a sample from the reported measures.
- **Benchmarking:** Validators must review all eligible populations and rates for each reported URAC measure against reported rates for prior years as well as those of other URAC-reporting pharmacy organizations. It is performed for each measure's sub-measure level (where applicable), aggregate level, and is specific to each product (e.g., Commercial, Medicaid, Medicare, Other) under review. During the course of benchmarking review, the validator may identify data trends that require the organization to provide source data (e.g., sampling) or other additional substantiation in order to support the reported eligible populations or rates.
- **Auxiliary Requests:** Requests for additional documentation may be made at the validator's discretion as long as such requests intend to verify the data elements captured within the accredited organization's transactions systems and assist in the determination of specific measure reporting capabilities.
- **Site Visit:** An on-site visit and review of the organization's URAC measure reporting capabilities must be performed by the validator. The site visit is typically one (1) day, but more than one (1) day may be required if there are multiple systems or locations that will be validated. (See Appendix D for sample agendas). The operational areas central to the site review include: claims, enrollment, distribution system, call center, data processing, acquisition and integration, and ancillary systems (as necessary). These operational areas will vary, depending on the type of organization and the measures required for reporting. The site visit will be a requirement for the first year of the validation program. If there are no significant pharmacy organization changes or review failures in the prior year, a site visit will not be mandatory for validation in the second and third years of measures validation cycle. Validators can use electronic methods to ensure validation in the second and third years of the measures data validation process.
- **Data Validation Report:** At the conclusion of the validation process, following the submission of final calculated measure submissions to URAC, the measures data

validation report will be submitted to pharmacy organizations. Pharmacy organizations will have an opportunity to provide report feedback to the validator prior to the report being finalized and submitted to URAC. The measures validation report will include the following sections:

- Validator attestation statement;
- Summary scope of validation, including products and mandatory and exploratory measures;
- Validation procedures section;
- Validator findings and recommendations; and
- Final approved eligible populations, rates and validation designations for each measure.

4. PROJECT SCOPE

The scope of this service is limited to the systems and data related to the pharmacy measures that the accredited organization is submitting to URAC for a given calendar year.

5. REQUIREMENTS

The chosen validators(s)/validation organizations must meet the following requirements:

1. Demonstrated proficiency in the audit tasks outlined in Description of Services above.
2. At least two years' experience in conducting similar health care audits.
3. Demonstrated ability to handle covered information (protected health information and/or personally identifiable information).
    a. Most recent security risk assessment and penetration analysis
    b. Sample Business Associate Contract/Agreement
    c. Sample notices of privacy practices
    d. Relevant privacy/security certifications (e.g., CIPP; HCISPP; CHPS; CHPC), with description of certification program.
4. Sufficient capacity to complete all validation tasks in accordance with timelines established by URAC. (See Appendix B). For the 2018 reporting period, there are approximately 250 organizations that will be required to report measures data to URAC.
5. Ability to demonstrate that the validator has any conflict of interest with the contracting accredited organizations covering a retrospective period of five (5) years.

6. Validation organizations must have certification/third party audit of the organization i.e., HITRUST, SOC 1 or 2 TYPE 2 review or other industry standard.

6. BUDGET

All proposals must include proposed typical pricing or pricing structure to complete the tasks described in the project scope. Pricing should be stated as one-time or non-recurring costs (NRC) or monthly recurring costs (MRC). Pricing should include each of the following items: Source System Review, Source Code Review, Data Extraction, Mapping Review, Benchmarking, Auxiliary Requests, Site Visit, and Validation Reporting.

NOTE: All costs and fees must be clearly described in each proposal. In addition, a three percent (3%) fee will be assessed of the validator or validation organization as required by and payable to URAC as per the agreement.

7. VALIDATION BIDDER QUALIFICATIONS (APPENDIX C)

Validation bidders should provide the following items as part of their proposal for consideration:

- Description of experience in providing similar health care validations (including, but not limited to: QRS audits, Medicare Part C & D Data Validation audits, and Risk Adjustment validation, etc.).
- Demonstration of at least two years' experience in validation health care management or pharmacy systems, data, and processes.
- Testimonials from past clients. (Minimum of three)
- Documentation of superior ability to protect covered information, as set forth in Section 5.3.a-d.
- Anticipated resources you will assign to validation tasks (total number, title, experience).
- Certification/third party audit of the organization i.e., HITRUST, SOC 1 or 2 TYPE 2 review or other industry standard.

8. URAC PROPOSAL EVALUATION CRITERIA

URAC will evaluate all proposals based on the following criteria. To ensure consideration for this Request for Proposal, your proposal should be complete and include all of the following criteria:

- Organizational Experience: Bidders will be evaluated on their experience as it pertains to the scope of this RFP.
- Previous work: Bidders will be evaluated on examples of their previous work based on description of validation services, client testimonials, and references

- Value and cost: Bidders will be evaluated on the cost of their services based on the work to be performed in accordance with the scope of this RFP.
- Technical qualifications: Bidders must provide descriptions and documentation of staff technical expertise and experience, as well as security and/or privacy certification(s) held.
- Certification/third party audit of the organization i.e., HITRUST, SOC 1 or 2 TYPE 2 review or other industry standard.

Questions/clarifications will be accepted at all points during the development of your response. Conference calls will be arranged upon request.

Each bidder must submit an electronic PDF copy of their proposal to the email address below on or before COB on December 15, 2017.

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9. APPENDIX A: VALIDATION TASKS

URAC Measure Data Validation Tasks

Measure Data Validation Program

As a requisite for URAC accreditation, organizations must fulfill an annual requirement for external measure data validation of annual URAC performance measure submission. The external validator will review the data collection and monitoring processes that enable the organization to report the measures. The validation encompasses multiple components, including review of the accredited organization's Information Systems Capacity Assessment (ISCA), submitted rates, sampling, and a site visit. A final determination of individual measure compliance / non-compliance with URAC reporting instructions will be established at the conclusion of the validation. The validator findings and final approved rates will be submitted to the accredited organizations and URAC in a final Measure Data Validation report.

Source/ Transaction Systems Review

Each of the pharmacy organization's source or transaction systems contributing data for URAC measure reporting will be covered by the validation. This includes each of the organization's source platforms where the reported denominator and numerator data originates from, including but not limited to: data repository/warehouse, enrollment or eligibility, prescription fulfillment, claims processing, and call center. The review of each system will be facilitated by the organization's submitted ISCA form, along with interviews and system demonstrations (in the first year of each organization's review and annually thereafter).

The systems review will consist of validation of all processes necessary for measure reporting, including data capture updates / conversions, process times, maintenance, quality assurance / audits, electronic / automation of process, specialized field capture, mapping and system edits.

Organizations are expected to capture the information necessary to report all measures accurately, within the materiality threshold. If the validator finds that the organization does not reliably capture adequate information to report a measure, that measure's reporting designation will indicate that a data capture problem exists. See the reporting designations section below for further information on the reporting designation.

Source Code Review

All programs, logs, macros and reference tables used for URAC reporting must be submitted to, reviewed by and approved by the validator. Calculations for the denominator and numerator and all sub-components for each internally developed measure, where applicable, will be validated for compliance.

Source code review is key to determine if any errors have been made in the reporting process. It is required for organizations to submit source code to their validator early in the reporting period. If material issues are identified by review of the code, organizations have the chance to correct the code and rerun rate calculations prior to final rate submission to URAC.

Validation Sampling

URAC requires that validators evaluate the organization's reported measures for overall data accuracy, missing information, invalid fields, implausible fields (e.g., range checks), demographic errors, stratification (if applicable), and other data aggregation failures. This validation step is accomplished by performing a process to reasonably extract and validate a source sample from the pharmacy organization reported measures.

For this validation sampling, validators must obtain and examine documentation from the primary source system for a sample from the reported measures. The validator will review source documentation from the organization's reporting platforms, identify any inaccuracies from the URAC reporting instructions, and work with the organization to resolve them. Substantive issues where there are, for example, material (e.g., > 10%) inaccuracies must be investigated and resolved. If organizations are unable to correct issues materially impacting the final rates, a non-material finding will result.

The URAC measure sample requirements for pharmacy organizations are as follows (See Appendix E for an example of the measure specifications for accredited organizations):

Measure	**Quantity**	**Denominator Fields**	**Numerator Fields**
Proportion of Days Covered	3 members per category: 30 total	Enrollment information: Effective date, End Date, DOB, member ID	Event (Claim) information: NDCs, Fill Dates, Days Supply, member ID
Adherence to Non-Warfarin Oral Anticoagulants	20 members	Enrollment information: Effective date, End Date, DOB, member ID	Event (Claim) information: NDCs, Fill Dates, Days Supply, member ID
Drug-Drug Interactions	20 members	Eligibility: Member ID , Effective date, end date, Fill date of precipitant medication, NDC	Event (Claim) information: NDC, Target medication Fill Date, member ID
Generic Dispensing Rates	NA	NA	NA
Call Center Performance	NA	NA	NA
Dispensing Accuracy	5 per category: 30 total	NA	Event information: Error category, DOS, Drug/Device dispensed.
Distribution Accuracy	15 per category: 30 total	NA	Event information: Error category, DOS, Drug/Device dispensed.
Turnaround Time for Prescriptions	15 per category: 30 total	Clean Rx flag/Intervention Rx Flag	Event information: Fill date, Delivery Date, Drug/Device Dispensed
Primary Medication Non-Adherence	10 Numerator Postive, 10 Numerator Negative: 20 total		
Use of High-Risk Medications in the Elderly	20 members	Enrollment information: Effective date, End Date, DOB, member ID	Event (Claim) information for 2 high risk drugs: Fill Dates, NDCs, member ID

The number of records sampled for each measure must not exceed the total sample size. For example, the 20-sample members selected for numerator review will be the same sample members used for denominator review.

Organizations may use either the random number or skip interval method to generate the sample. Validators will review the sampling process used by the accredited organization. If using the random number method, follow this process:

1. Add a column to the left of the 1st column of raw data and label in RAND.
2. Enter the formula =RAND()
3. Copy this formula down all rows with data (not the header row).
4. Copy the values and select paste values.
5. Sort from lowest to highest (ascending 0-9, A-Z order) and pick the number of records requested from the top of the list.

If using skip interval, follow this process:

	Called	Example
1. Sort the order of the record set by the unique identifier (i.e. member ID, prescription claim ID, etc.) ascending 0-9, A-Z.		
2. Obtain count of events reported by the Organization for the measure or sub-measure	N	1,000
3. URAC specified sample size.	S	20
4. Divide **N** by **S**, truncate (round down) result to find the Interval.	I	50
5. Start Point is **I** divided by 5 and truncated (rounded down).	SP	10
6. Beginning with the **SP**, count to the next interval and select records until you have the full sample.		10, 20, 30s, etc.

Validators may use discretion in regard to expanding the sample review to include additional product lines (e.g., Commercial, Medicare, Medicaid), however, if reporting processes are the same across all product lines, only one product is required to be reviewed for samples for each measure. Additionally, if affiliates or subsidiaries of the same parent organization share the same underlying systems, use them in substantially the same manner and reporting is consistent across organizations, one sample may be take across organizations.

Organizations will submit samples to validators for review. The sample review must be completed prior to the final rate submission to URAC. Sample review may identify errors in the reporting process, so it is highly encouraged for plans to submit samples to their validator early in the reporting period. Corrections to any material issues identified by sample review must be completed prior to final rate submission to URAC.

Benchmarking

Benchmarking is the process by which validators review all eligible populations and rates for each reported URAC measure against reported rates for prior years as well as those of other URAC-reporting organizations. It is performed for each measure's sub-measure level (where applicable), aggregate level, and is specific to each product (e.g., Commercial, Medicaid, Medicare, Other) under review. Each comparison to the organization's prior year reporting and other accredited organizations' reporting performance is intended to support the validator's final validation designation for each URAC measure.

During the course of benchmarking review, the validator may identify data trends that require the organization to provide source data (e.g., sampling) or other additional substantiation in order to support the reported eligible populations or rates. For example, in order to validate a measure's eligible population that increased more than 10% from the prior year, the validator could request a sample of source documentation that validates that measure denominator requirements are appropriately being met from the organization enrollment or prescription claims system. Similarly, an organization's reported URAC rate that benchmarks significantly lower than other organizations' reported rates for the same measure might suggest that the pharmacy organization may need to provide the validator with source reports for total prescription claims dispensed via retail or mail service to ensure the organization is properly capturing all data required for compliance with the measure's distinct numerator reporting specifications. Validators will use their discretion to determine the most appropriate steps to satisfactorily complete the benchmarking review.

Submission of Preliminary rates for benchmarking is required, and it is suggested that this occur early in the reporting process. Questions identified during rate investigation must be adequately closed prior to final rate submission to URAC. Material errors identified during rate investigation must be corrected prior to final rate submission to URAC, or the rate will be identified as materially inaccurate.

Site Visit

A site visit and review of the pharmacy organization's URAC measure reporting capabilities will be performed by the validator. The site visit is typically one (1) day, but more than one (1) day may be required if there are multiple systems or locations that will be visited. The operational areas central to the site review include: claims, enrollment, distribution system, call center, data processing, acquisition and integration. These operational areas will vary, depending on the type of organization and the measures required for reporting. The site visit will be a requirement for the first year of the validation. If there are no significant pharmacy organization changes or review failures in the prior year, a site visit will not be mandatory for the validation in the second and third years of measure data validation cycle. For organizations with affiliates or subsidiaries, if all of the source/ transaction systems used in reporting were reviewed at an affiliate's or parent's site visit in the prior year or prior two years, then no site visit is required for the affiliate or subsidiary. Subsequent year site visits will be periodic, or the validator may elect to conduct telephonic or web based interactions. A site agenda template designed to cover each of the main components in the ISCA will be provided by the validator.

Validation Report

At the conclusion of the validation, following the submission of final calculated measure submissions to URAC, the validation report will be submitted to the accredited organizations. Organizations will have an opportunity to provide validation report feedback to the validator prior to the report being finalized and submitted to URAC. The validation report will include the following sections:

- Validator attestation statement;
- Summary scope of validation, including products and mandatory and exploratory measures;
- Validation procedures section;
- Validator findings and recommendations; and
- Final approved eligible populations, rates and validation designations for each measure.

The validator will submit the draft validation report to Organizations when the final rates are reported to URAC. Organizations may submit validation report comments to the validator. The final copy of the validation report is due to Organizations and URAC one month after the final rates are due.

Materiality

In order to determine whether any of the validator review findings related to any of the validation tasks represents a material impact on URAC reporting compliance, a materiality threshold of 10% will be applied. This applies to review of both numerator and denominator components for each individual measure. The 10% threshold will also be applied towards each individual measure's separate sub-measure, if applicable. For example, each of the reported stratifications for the Generic Dispensing Rates measure (e.g. Commercial, Medicaid, Medicare, and Other) would have their own individual application of the 10% standard for the numerator and denominator for the measurement period. As another example, for the Proportion of Days Covered Measure, each of the 10 drug categories who met the 80% PDC threshold would be individually subject to the 10% materiality threshold.
For each instance of validator task review where it is determined there is a material finding, there will be documentation in the pharmacy organization validation report. The appropriate validation designation of materially incorrect will then be applied to each affected measure.

Validation Designations

URAC Accredited pharmacy organizations are required to report all Mandatory measures. Mandatory measures are identified annually by URAC. The following Validation designations will be used by the validator to indicate the reporting status of the Mandatory measures.
Materially Accurate – the population and rate is materially accurate.
Materially Inaccurate – an element of the mandatory measure is materially inaccurate.
Not able to report – the accredited organization does not adequately capture the information necessary to report the measure. An explanation for why the organization was unable to report a measure must be included in the final validation report.

Glossary of Terms

Validation Designations – Validators will indicate validation findings by measure by the use of Validation designations. All measures that are part of the required performance measure set for accreditation must have a final, validated result. The validator approves the compliance/non-compliance of each mandatory measure in scope for the validation.
Information Systems Capacity Assessment (ISCA) – Form that requires accredited organizations to describe the policies, processes, and data quality control procedures, that is used to formulate a determination of the organization ability to support the accurate and reliable calculation of the performance measures set.
Materiality Threshold - The acceptable level of error before which information under review is determined to be materially incorrect. If an organizations data is found to be materially incorrect, they will not be able to report the affected measures to URAC. This concept is used in determining a measure's validation designation.
Preliminary Rates - The initial rate data submitted to URAC by accredited organizations via the designated portal, including measure reporting in the URAC reporting template format. This enables the validator to perform benchmarking review, as a necessary step of the URAC measure data validation.
Rate Benchmarking - The process by which validators review all eligible populations and rates for each reported URAC measure against prior year reported rates and other URAC reporting accredited organizations.
Remedial Actions – Steps an accredited organization may take to ensure URAC performance measure reporting appropriately follows URAC guidelines and specifications.
Sampling – The validation step that utilizes a process to reasonably extract and validate a source sample from the accredited organization reported measures. Supporting sample documentation originates directly from the organization reporting platform (e.g. claims, enrollment) and is submitted to the validator for review.
Site Visit – Typically, a one-day site visit with the accredited organization where the validator reviews operational areas essential to URAC reporting, including claims, enrollment, distribution system, call center, data processing, acquisition and integration, and ancillary systems as necessary.
Submission Portal – The mechanism by which an accredited organizations must submit their measurement data to URAC.

10. APPENDIX B: TIMELINE

URAC Measure Data Validation Timeline

The measure data validation will be conducted concurrently to the organization's reporting activities. The goal of the validation is to ensure that accurate, reliable and comparable quality measure data is reported to URAC. The validation program is flexible except where indicated and should be negotiated with the client. The following timeline is an example:

Task	Deadline
Organization contract with qualified data validator	March 31
Project initiation and kick off	May 31
Organization submit system information to validators, including all supporting documentation and source code	July 1
Validator completes documentation review	July 15
Organization submit preliminary rates to Validator	July 1
Organization submit samples to Validator	July 15
Validator conducts site visits or virtual reviews	July 1 – September 15
Validator completes sample review	September 15
Organization submits final rates to URAC and Validator	September 30 (non-negotiable)
Validator submits draft validation report to Organization	September 30 (non-negotiable)
Organization submits comments on draft validation report to validator	October 7
Validator submits finalized validation report to Organizations and URAC	October 15 (non-negotiable)

11. APPENDIX C: SELECTION CRITERIA FOR ACCREDITED ORGANIZATIONS

Criteria for Selecting a Measure Data Validation Organization

1) URAC Approved Measure Data Validation Organizations

Accredited Organizations are required to select and contract with an independent organization from the URAC approved list of Measure Data Validation Organizations.

2) Vendor Qualifications

Organizations must select a measure data validator who has proficiency and at least two years' experience in conducting similar health care audits. Similar validation activities include QRS Quality audits, Medicare Part C and D Data Validation audits and Risk Adjustment audits.

The organization must select a measure data validator who has familiarity and at least two years' experience in auditing or validating systems, data and processes.

The organization must select a Measure Data Validation Organization who has demonstrated ability to securely handle covered information (protected health information and/or personally identifiable information). The Measure Data Validation Organization should hold third party certification such as HITRUST CSF or current SOC Type 2 audit.

The organization must select a Measure Data Validation Organization with sufficient capacity to complete the validation in the timeline specified by URAC.

3) Standard for Independence

URAC accredited organizations must select an independent, external entity to conduct their data validation. In order to ensure the independence of the validation, the organization may not use internal staff. The Measure Data Validation must be conducted by an independent entity that is not employed, contracted, sub-contracted, represented or considered to be a first-tier, downstream, or related entity by the organization per Federal Regulations at 42 CFR § 422.500 and § 423.501.

The Measure Data Validation Organization cannot have provided any management consulting, data improvement, rate improvement, or other improvement activities for the accredited organization over the past five years.

The Measure Data Validation Organization must be free of any conflict of interest. The Measure Data Validation Organization may not have worked for the organization subject to validation anytime in the last five years. The Measure Data Validator may not have any ownership interest in the accredited organization or any other financial interest in the organization. Measure Data Validators who have consulted with the organization on improvement of information systems used in any part of the URAC reporting process are conflicted for a minimum period of five years. Depending on the scope of the consulting engagement, conflicts may still exist even after five years and must be reviewed on a case by case basis.

Measure Data Validation Organizations who have conducted other data validation or compliance validation services for the accredited organization are not considered conflicted.

4) Contracting with a Data Validation Organization

Accredited Organizations may contract with a Measure Data Validation Organization any time prior to the contracting deadline found within the URAC Measure Data Validation Timeline.

12. APPENDIX D: SAMPLE AGENDAS FOR ACCREDITED ORGANIZATIONS

URAC Pharmacy Measure Data Validation Sample 1: PBM, Mail Order or Drug Therapy Management Agenda

9:30 – 10:00	***Opening Session***
	Introductions, Review of Agenda, Discussion of URAC Pharmacy Measure Data Validation progress, and open forum for agenda additions
10:00 – 10:30	***Benchmarking Review***
	Review preliminary rates. Discuss organization factors for rate outliers.
10:30 – 11:15	***Claims/ Scripts***
	ISCA Section 4.0, 5.0 Content, claim form utilization type(s), homegrown/global billing codes, claims data fields maintenance, coding schemes, system edits, QA/validation/audits, system adjudication, status (e.g. pended, denied), copay tiers, therapeutic class, eligibility verification, outside parties/contractors, time to process, EDI process, upgrades/conversions ➢ System Demo – need to see how claims are captured in the system. Will review data fields and how tied to a member.
11:15 – 12:00	***Enrollment (If necessary)***
	➢ ISCA Section 6.0 Content, eligibility QA process, member ID, product lines linkage, enrollment information/records updates, spans, continuous enrollment algorithm, enroll/dis-enroll policy, system upgrades/conversions, enrollment data type/frequency, time-to-process, enrollment-data source reconciliation, QA/audits, enrollment fields captureSystem demo – need to see how enrollment spans and benefit codes are maintained in the system. Will review fields captured
12:00 – 1:00	***Lunch Break***
1:00 – 1:30	***Distribution system accuracy***
	ISCA Section 4.0 Content, source for reporting Dispensing Accuracy, source for reporting Distribution Accuracy
1:30 – 2:00	***Call Center***
	ISCA Section 3.0 Content, call/ACD system, types of calls

	processed/queues, abandoned calls, average speed to answer, captured call data elements, system parameters/settings, volume reports, source code/ACD reports for URAC measure calculation ➢
2:30 – 3:30	***Data Processing, Acquisition and Integration***
	ISCA Section 2.0, 4.0, 5.0 Content, Data integration, repository and warehouse maintenance, programming to produce measures, data system upgrades/conversions, organization URAC performance measure requirements, backup/recovery, physical security, ETL process, quality control, logic process for URAC measure calculations, data completeness ➢
3:30 – 4:00	***Auditor Prep for Closing Session***
4:00 – 4:30	***Closing Session***
	Onsite visit summary, review of completed audit components, and discussion of upcoming URAC Pharmacy Audit tasks. Open forum to address any plan needs or questions.

Sample 2: Specialty Pharmacy Agenda

9:30 – 10:00	***Opening Session***
	Introductions, Review of Agenda, Discussion of URAC Pharmacy Measure Data Validation progress, and open forum for agenda additions
10:00 – 10:30	***Call Center Measure***
	Review preliminary rates. Review call center reports. Discuss other factors impacting reporting
10:30 – 11:00	***Distribution/ Dispensing Accuracy***
	Review preliminary rates. Discuss/ demo data capture system. Discuss QA/validation/audits, upgrades/conversions. Discuss reporting process and source code.
11:00 – 12:00	***Drug-Drug Interaction/ Turnaround Time for Prescriptions***
	ISCA Section 4.0, 5.0 Content, dispensing system demo, forms data fields, coding schemes, system edits, QA/validation/audits, order date, fill date, time to process, EDI process, upgrades/conversions ➢ System Demo – need to see how scripts are processed in the system. Will review data fields and how tied to a member.
12:00 – 12:45	***Lunch Break***
12:45 – 1:00	***Validator prep for Exit***
1:00 – 2:00	***Exit Conference, Next Steps***

Measure DM2012-12: Proportion of Days Covered (PDC) [E]

Steward	**URAC Domain**	**Data Source**
Pharmacy Quality Alliance (Reprinted with Permission)	Engagement & Experience of Care	Pharmacy Claims; Enrollment Data

Description

The percentage of patients 18 years and older who met the proportion of days covered (PDC) threshold of 80% during the measurement year. A performance rate is calculated separately for the following medication categories: Beta-blockers (BB); Renin Angiotensin System (RAS) Antagonists; Calcium Channel Blockers (CCB); Statins; Biguanides; Sulfonylureas; Thiazolidinediones; Dipeptidyl Peptidase (DPP)-IV Inhibitors; Diabetes All Class; Anti-retrovirals (this measure has a threshold of 90% for at least 2 measures). **[E]**

Rationale

Medications are the primary therapy for the most common diseases afflicting persons in the United States. There is evidence to support improvements in health for patients who are adherent to medications. For patients who have had a myocardial infarction, those who achieved adherence to statins, beta-blockers and angiotensin converting enzyme/angiotensin receptor blockers (ACE/ARBs), measured by proportion of days covered (PDC) greater than 80% had significantly better disease-free survival. (Choudhry et al., 2014)

Specifications Definitions

PDC: The proportion of days in the measurement period "covered" by prescription claims for the same medication or another in its therapeutic category.
PDC Threshold: The level of PDC above which the medication has a reasonable likelihood of achieving most of the potential clinical benefit (80% for diabetes and cardiovascular drugs; 90% for antiretroviral).

Eligible Population

Ages: 18 years and older as of the last day of the measurement period.

Continuous Enrollment: Using enrollment data: Subjects should be continuously enrolled during the measurement period. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the member may not have more than a 1-month gap in coverage (i.e., a member whose coverage lapses for 2 months [60 consecutive days] is not considered continuously enrolled).

Measurement Period: The patient's measurement period begins on the date of the first fill of the target medication (i.e., index date) and extends through the last day of the enrollment period or until death or disenrollment. The index date should occur at least 91 days before the end of the enrollment period.

Stratification: Commercial, Medicaid, Medicare (report each product line separately).

Administrative Specification

Report each of the rates separately. Patients may be counted in the denominator for multiple rates if they have been dispensed the relevant medications. For each rate, however, proportion of days covered should only be counted once per patient.

Additional Eligible Population Criteria: Patients who filled at least two prescriptions of the specified drug on two unique dates of service during the measurement period.

Measure DM2012-12: Reporting Specifications

Rate 1: Beta-Blocker (BB) Medications

Rate: Numerator/denominator x 100%

Denominator: Patients 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a beta-blocker or beta-blocker combination (Table-PCD-A: Beta-Blocker Medications) on two unique dates of service during the measurement period.

Exclusion Criteria: *N/A*

Numerator: The number of patients who met the PDC threshold of 80% during the measurement year.

Exclusion Criteria: *N/A*

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the enrollment year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC greater than 80% and then divide by the total number of eligible patients.

* Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-A: Beta-Blocker (BB) Medications

BB Medications			
acebutolol HCL atenolol betaxolol HCL bisoprolol fumarate	carvedilol labetalol HCL metoprolol succinate	metoprolol tartrate nadolol nebivolol HCL penbutolol sulfate	pindolol propranolol HCL timolol maleate

BB Combination Products		
atenolol & chlorthalidone bisoprolol & HCTZ	nadolol & bendroflumethiazide metoprolol & HCTZ	propranolol & HCTZ

Note: Active ingredients are limited to oral formulations only. Excludes the BB sotalol because it is indicated for the treatment of ventricular arrhythmias (and not for hypertension). Excludes nutritional supplement/dietary management combination products.

Measure DM2012-12: Reporting Template

Rate 1: Beta Blocker (BB) Medications

Stratification	***Numerator:*** The number of patients who met the PDC threshold of 80% during the measurement year.	***Denominator:*** Patients 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a beta-blocker or beta-blocker combination (Table-PCD-A: Beta-Blocker Medications) on two unique dates of service during the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure, or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 2: Renin Angiotensin System (RAS) Antagonists

Rate: Numerator/denominator x 100%

Denominator: Patients who filled at least two prescriptions for a RAS Antagonist: ACEI/ARB/Direct Renin Inhibitor or ACEI/ARB/Direct Renin Inhibitor Combination (Table PDC-B: RAS Antagonists) on two unique dates of service during the measurement period.

Exclusion Criteria: Patients with ESRD* or with one or more prescription claims for the medication sacubitril/valsartan.

* Patient with ESRD can be identified using:

- RxHCC 121 – Dialysis Status (for Payment Year 2015) or;
- RxHCC 261 – Dialysis Status (for Payment Year 2016) or;

Using the ICD-10 codes in Appendix F: Table ESRD.

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-B: Renin Angiotensin System (RAS) Antagonists

Direct Renin Inhibitor Medications				
aliskiren				
ARB Medications				
candesartan eprosartan	irbesartan losartan	olmesartan telmisartan	valsartan azilsartan	
ACE Inhibitor Medications				
benazepril captopril	enalapril fosinopril	lisinopril moexipril	perindopril quinapril	ramipril trandolapril
ACE Inhibitor Combination Products				
amlodipine & benazepril benazepril & HCTZ	enalpril & HCTZ fosinopril & HCTZ	lisinopril & HCTZ moexipril & HCTZ	quinapril & HCTZ trandolapril-verapamil	

captopril & HCTZ		perindopril & amlodipine	HCL
ARB Combination Products			
candesartan & HCTZ eprosartan & HCTZ telmisartan & almodipine	irbesartan & HCTZ losartan & HCTZ amlodipine & olmesartan azilsartan & chlorthalidone	olmesartan & HCTZ telmisartan & HCTZ aliskiren & valsartan olmesartan & amlodipine & HCTZ	valsartan & HCTZ amlodipine & valsartan amlodipine & valsartan & HCTZ
Direct Renin Combination Products			
aliskiren & amlodipine	aliskiren & amlodipine & HCTZ	aliskiren & HCTZ	

Note: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Measure DM2012-12: Reporting Template

Rate 2: Renin Angiotensin System (RAS) Antagonists

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled two or more prescriptions on two unique dates of service during the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure, or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 3: Calcium Channel Blocker (CCB) Medications

Rate: Numerator/denominator x 100%

Denominator: Patients who filled at least two prescriptions for a calcium channel blocker or CCB combination (Table PDC-C: Calcium-Channel Blocker Medications) on two unique dates of service in the measurement period.
Exclusion Criteria: N/A

Numerator: The number of patients who met the PDC threshold during the measurement year.
Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

- ***Step 1*** Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.
- ***Step 2*** Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*
- ***Step 3*** Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.
- ***Step 4*** Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-C: Calcium-Channel Blocker (CCB) Medications

CCB Medications			
amlodipine besylate diltiazem HCL	felodipine isradipine	nicardipine HCL nifedipine (long acting only)	verapamil HCL nisoldipine

CCB Combination Products		
amlodipine besylate & benazepril HCL amlodipine & valsartan amlodipine & valsartan & HCTZ akiskiren & amlodipine	akiskiren & amlodipine & HCTZ telmisartan & amlodipine amlodipine & olmesartan	trandolapril & verapamil HCL amlodipine & atorvastatin olmesartan & amlodipine & HCTZ

Note: Active ingredients are limited to oral formulations only. Excludes CCB nimodipine since it has a limited indication for use following a subarachnoid hemorrhage. Excludes nutritional supplement/dietary management combination products.

Measure DM2012-12: Reporting Template

Rate 3: Calcium Channel Blocker (CCB) Medications

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a calcium channel blocker or CCB combination on two unique dates of service in the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 4: Biguanides

Rate: Numerator/denominator x 100%

Denominator: Patients, 18 years or older who filled at least two prescriptions for a biguanide or biguanide combination product (Table PDC-DL Biguanide Medications) on two unique dates of service in the measurement period.

Exclusion Criteria:

- Patients who have one or more prescriptions for insulin in the measurement period (refer to Table PDC-H shown in Rate 8).
- Patients with ESRD*.

* Patient with ESRD can be identified using:

- RxHCC 121 – Dialysis Status (for Payment Year 2015) or;
- RxHCC 261 – Dialysis Status (for Payment Year 2016) or;
- ICD-10 codes in Appendix F: Table ESRD.

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-D: Biguanide Medications

Biguanides	
metformin	
Biguanides & Sulfonylurea Combination Products	
glipizide & metformin	glyburide & metformin
Biguanides & Thiazolinedione Combination Products	
rosiglitazone & metformin	pioglitazone & metformin
Biguanides & Meglitinide Combinations	
repaglinide & metformin	
Biguanides & DPP-IV Inhibitor Combinations	
sitagliptin & metformin IR & SR saxagliptin & metformin SR	linagliptin & metformin alogliptin & metformin

Biguanides & SGLT2 Inhibitor Combinations	
dapagliflozin & metformin	canagliflozin & metformin empagliflozin & metformin

Note: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Measure DM2012-12: Reporting Template

Rate 4: Biguanides

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a biguanide or biguanide combination product on two unique dates of service in the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 5: Sulfonylureas

Rate: Numerator/denominator x 100%

Denominator: Patients, 18 years or older who filled at least two prescriptions for a sulfonylurea or sufonylurea combination (Table PDC-E: Sulfonylurea Medications) on two unique dates of service in the measurement period.

Exclusion Criteria:

- Patients who have one or more prescriptions for insulin in the measurement period (refer to Table PDC-H shown in Rate 8).
- Patients with ESRD*.

* Patient with ESRD can be identified using:

- RxHCC 121 – Dialysis Status (for Payment Year 2015) or;
- RxHCC 261 – Dialysis Status (for Payment Year 2016) or;
- Using the ICD-10 codes in Appendix F: Table ESRD.

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-E: Sulfonylurea Medications

Sulfonylureas		
chlorpropamide glimepiride	glipizide glyburide	tolazamide tolbutamide
Sulfonylurea & Biguanide Combination Products		
glipizide & metformin	glyburide & metformin	
Sulfonylurea & Thiazolidinedione Combination Products		
rosiglitazone & glimepiride	pioglitazone & glimepiride	

Note: Active ingredients are limited to oral formulations only (includes all salts and dosage forms).

Measure DM2012-12: Reporting Template			
Rate 5: Sulfonylureas			
Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a sulfonylurea or sufonylurea combination on two unique dates of service in the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 6: Thiazolidinediones

Rate: Numerator/denominator x 100%

Denominator: Patients, 18 years and older who filled at least two prescriptions for a thiazolidinedione (Table PDC-F: Thiazolidinedione Medications) on two unique dates of service in the measurement period.

Exclusion Criteria:

- Patients who have one or more prescriptions for insulin in the measurement period (refer to Table PDC-H shown in Rate 8).
- Patients with ESRD*.

* Patient with ESRD can be identified using:

- RxHCC 121 – Dialysis Status (for Payment Year 2015) or
- RxHCC 261 – Dialysis Status (for Payment Year 2016) or
- Using the ICD-10 codes in Appendix F: Table ESRD

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-F: Thiazolidinedione Medications

Thiazolidinediones	
pioglitazone	rosiglitazone
Thiazolidinediones & Biguanide Combination Products	
rosiglitazone & metformin	pioglitazone & metformin
Thiazolidinediones & Sulfonylurea Combination Products	
rosiglitazone & glimepiride	pioglitazone & glimepiride
Thiazolidinediones & DPP IV Inhibitor Combination Products	
alogliptin & pioglitazone	

Note: Active ingredients are limited to oral formulations only.

Measure DM2012-12: Reporting Template

Rate 6: Thiazolidinediones

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a thiazolidinedione on two unique dates of service in the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 7: DPP-IV Inhibitors

Rate: Numerator/denominator x 100%

Denominator: Patients, 18 years or older who filled at least two prescriptions for a DPP-IV (Table PDC-G: DPP-IV Inhibitor Medications) on two unique dates of service in the measurement period.

Exclusion Criteria:

- Patients who have one or more prescriptions for insulin in the measurement period (refer to Table PDC-H shown in Rate 8).
- Patients with ESRD*.

* Patient with ESRD can be identified using:

- RxHCC 121 – Dialysis Status (for Payment Year 2015) or;
- RxHCC 261 – Dialysis Status (for Payment Year 2016) or;
- Using the ICD-10 codes in Appendix F: Table ESRD.

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-G: DPP-IV Inhibitor Medications

DPP-IV Inhibitors		
sitagliptin linagliptin	saxagliptin alogliptin	
DPP-IV Inhibitor Combination Products		
sitagliptin & metformin IR & SR saxagliptin & metformin SR	sitagliptin & simvastatin linagliptin & metformin	alogliptin & metformin alogliptin & pioglitazone empagliflozin & linagliptin

Note: Active ingredients are limited to oral formulations only. **Measure DM2012-12: Reporting Template**

Rate 7: DPP-IV Inhibitors

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a DPP-IV on two unique dates of service in the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 8: Diabetes All Class Rate

Rate: Numerator/denominator x 100%

Denominator: Patients, 18 years or older who filled at least two prescriptions for any of the diabetes medications listed in Tables PDC-D, PDC-E, PDC-F, PDC-G, PDC-J, PDC-K, or PDC-L on two unique dates of service in the measurement period. The prescription can be for the same or different medications, and can be from any of these seven tables.

Exclusion Criteria:

- Patients who have one or more prescriptions for insulin in the measurement period (refer to Table PDC-H).
- Patients with ESRD*.

* Patient with ESRD can be identified using:

- RxHCC 121 – Dialysis Status (for Payment Year 2015) or;
- RxHCC 261 – Dialysis Status (for Payment Year 2016) or;
- Using the ICD-10 codes in Appendix F: Table ESRD.

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the enrollment year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug from any of the diabetes drugs listed in PDC Tables D-G, J, K, or L based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-D: Biguanide Medications

Biguanides	
metformin	
Biguanides & Sulfonylurea Combination Products	
glipizide & metformin	glyburide & metformin
Biguanides & Thiazolinedione Combination Products	
rosiglitazone & metformin	pioglitazone & metformin
Biguanides & Meglitinide Combinations	
repaglinide & metformin	

Biguanides & DPP-IV Inhibitor Combinations	
sitagliptin & metformin IR & SR saxagliptin & metformin SR	linagliptin & metformin alogliptin & metformin
Biguanides & SGLT2 Inhibitor Combinations	
dapagliflozin & metformin	canagliflozin & metformin empagliflozin & metformin

Note: Active ingredients are limited to oral formulations only. Excludes nutritional supplement/dietary management combination products.

Table PDC-E: Sulfonylurea Medications

Sulfonylureas		
chlorpropamide glimepiride	glipizide glyburide	tolazamide tolbutamide
Sulfonylurea & Biguanide Combination Products		
glipizide & metformin	glyburide & metformin	
Sulfonylurea & Thiazolidinedione Combination Products		
rosiglitazone & glimepiride	pioglitazone & glimepiride	

Note: Active ingredients are limited to oral formulations only (includes all salts and dosage forms).

Table PDC-F: Thiazolidinedione Medications

Thiazolidinediones	
pioglitazone	rosiglitazone
Thiazolidinediones & Biguanide Combination Products	
rosiglitazone & metformin	pioglitazone & metformin
Thiazolidinediones & Sulfonylurea Combination Products	
rosiglitazone & glimepiride	pioglitazone & glimepiride
Thiazolidinediones & DPP IV Inhibitor Combination Products	
alogliptin & pioglitazone	

Note: Active ingredients are limited to oral formulations only.

Table PDC-G: DPP-IV Inhibitor Medications

DPP-IV Inhibitors		
sitagliptin linagliptin	saxagliptin alogliptin	
DPP-IV Inhibitor Combination Products		
sitagliptin & metformin IR & SR saxagliptin & metformin SR	sitagliptin & simvastatin linagliptin & metformin	alogliptin & metformin alogliptin & pioglitazone empagliflozin & linagliptin

Note: Active ingredients are limited to oral formulations only.

Table PDC-J: Incretin Mimetic Agents

Incretin Mimetic Agents			
albiglutide	exenatide	liraglutide	dulaglutide

Table PDC-K: Meglitinides

Meglitinides		
nateglinide	repaglinide repaglinide & metformin	

Note: Active ingredients are limited to oral formulations only.

Table PDC-L: Sodium glucose co-transporter2 (SGLT2) inhibitors

SGLT2 Inhibitors

canagliflozin	dapagflozin	empagliflozin
dapagliflozin & metformin empagliflozin & linagliptin	canagliflozin & metformin empagliflozin & metformin	

Note: Active ingredients are limited to oral formulations only.

Table PDC-H: Insulins (Exclusion Table)

Human Insulins	
insulin aspart	insulin isophane & regular human insulin
insulin aspart Protamine & Aspart	insulin isophane (human N)
insulin detemir	insulin lispro
insulin glargine	insulin lispro Protamine & Insulin lispro
insulin glulisine	insulin regular (human R)
insulin regular (human) inhalation powder	insulin degludec

Note: Active ingredients are limited to injectable and inhaled formulations only.

Measure DM2012-12: Reporting Template

Rate 8: Diabetes All Class Rate

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for any of the diabetes medications listed in Tables PDC-D, PDC-E, PDC-F, PDC-G, PDC-J, PDC-K, or PDC-L on two unique dates of service in the measurement period.	***Rate***
Across all Commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 9: Statins

Rate: Numerator/denominator x 100%

Denominator: Patients who filled at least two prescriptions for a statin or statin combination (Table PDC-I: Statin Medications) on two unique dates of service in the measurement period.

Exclusion Criteria: *N/A*

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-I: Statin Medications

Statin Medications			
lovastatin rosuvastatin	fluvastatin atorvastatin	pravastatin pitavastatin	simvastatin
Statin Combination Products			
niacin & lovastatin atorvastatin & amlodipine	niacin & simvastatin sitagliptin & simvastatin	ezetimibe & simvastatin ezetimibe & atorvastatin	

Note: The active ingredients are limited to oral formulations only.

Measure DM2012-12: Reporting Template

Rate 9: Statins

Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled at least two prescriptions for a statin or statin combination (Table PDC-I: Statin Medications) on two unique dates of service in the measurement period.	***Rate***
Across all commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that your organization will be required to report by stratified categories in 2019. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.

Measure DM2012-12: Reporting Specifications

Rate 10: Anti-Retroviral Medications

Rate: Numerator/denominator x 100%

Denominator: Patients who filled a prescription for at least two individual drugs (as a single agent or as a combination) listed in Table PDC-Antiretroviral medication on two unique dates of service in the measurement period.

Exclusion Criteria: *N/A*

Numerator: The number of patients who met the PDC threshold during the measurement year.

Exclusion Criteria: N/A

NOTE: Follow the steps below to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the calendar year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by **two or more** distinct antiretroviral drugs (refer to Table PDC – Antiretroviral-A) in the class based on the prescription fill date and days of supply. If prescriptions for the same target drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 90% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single drug or when there is an overlap of a combination product to another combination product where at least one of the target drugs is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: http://www2.sas.com/proceedings/forum2007/043-2007.pdf

Table PDC-Antiretroviral-A: Antiretrovirals

Antiretroviral Medications			
Single Agents: Enfuvirtide Maraviroc Atazanavir Darunavir Fosamprenavir Indinavir	Nelfinavir Ritonavir Saquinavir Tipranavir Dolutegravir Raltegravir	Delavirdine Efavirenz Etravirine Nevirapine Abacavir Didanosine	Emtricitabine Lamivudine Stavudine Tenofovir Zidovudine Rilpivirine Elvitegravir
Combination Agents: Lopinavir & Ritonavir Lamivudine & zidovudine Darunavir & Cobicistat Atazanavir & Cobicistat	Abacavir, Lamivudine, & Zidovudine Efavirenz, emtricitabine, & tenofovir	Emtricitabine & tenofovir Abacavir & lamivudine Emtricitabine & rilpivirine & tenofovir	Elvitegravir & cobicistat & emtricitabine & tenofovir Abacavir & dolutegravir & lamivudine

Note: Active ingredients are limited to oral and subcutaneous formulations only.
*Excludes zidovudine IV and lamivudine 100mg (Epivir HBV 100mg).

Measure DM2012-12: Reporting Template			
Rate 10: Anti-Retroviral Medications			
Stratification	***Numerator:*** The number of patients who met the PDC threshold during the measurement year.	***Denominator:*** Members 18 years and older as of the last day of the measurement year who filled a prescription for at least two individual drugs (as a single agent or as a combination) listed in Table PDC-Antiretroviral medication on two unique dates of service in the measurement period.	***Rate***
Across all commercial programs			
Across all Medicaid programs			
Across all Medicare programs			
Across all Other* populations			
Please provide any additional information unique to your organization that you think might impact your results.			

*Note: If this is your first year reporting measures data to URAC and your system cannot stratify this measure by commercial, Medicaid, and Medicare, please report the combined categories under 'Other'. Please note that in 2019 your organization will be required to report by stratified categories. If your system can stratify this measure or this is not your first year reporting data to URAC, please do not report any data under 'Other'.