BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, DC 20005
www.BCBS.com

June 23, 2014

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer

Re: Agency Information Collection Activities: Submission for OMB Review; Comment Request (**Document Identifier: CMS–10520**)

To: OMB Desk Officer for CMS

The Blue Cross and Blue Shield Association (BCBSA) – a national federation of 37 independent, community-based, and locally operated Blue Cross and Blue Shield companies ("Plans") that collectively provide healthcare coverage for 100 million members, one in three Americans – appreciates the opportunity to submit comments on the Paperwork Reduction Act (PRA) request addressing estimated cost and burden associated with collecting and reporting the information required by the Qualified Health Plans (QHP) participating in the health care exchange(s) as issued in the *Federal Register* on May 20, 2014.

As a significant stakeholder in the Health Insurance Marketplace – BCBS Plans offer coverage through the Marketplaces in 47 states – we share your goal of providing sound, reliable, and meaningful quality-related information to consumers to help them identify and choose the highest quality health insurance products. Our comments are informed by BCBSA's and Plans' extensive experience in partnering with network providers to improve the quality, safety, and affordability of healthcare.

While we support the desire of CMS to report quality measures and patient survey results on Marketplace products, we have significant concerns about the collection, validation, and submission of the data required to implement the Federal Quality Rating System (QRS) – in particular the 31 clinical quality measures that comprise CMS's current QRS measure set (posted May 16, 2014). Pursuant to the PRA request, we wish to offer comments regarding (1) the accuracy of the estimated burden; (2) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; and (3) ways to enhance the quality, utility, and clarity of the information to be collected.

- **First, the required implementation costs are substantially higher than the estimates provided by CMS.** As noted in greater detail below, the estimates that CMS has documented for data collection and reporting for the QRS are significantly understated compared with Plan experience. We recommend that CMS re-visit their estimate using the final quality measure list and include the additional costs incurred through use of hybrid measures and implementation of new measures.

- **Second, the current QRS measures will not support proper performance of the agency's functions because of problems with the measures' feasibility, reliability, or validity.** In general, we are concerned about using hybrid measures in 2016 because of sampling issues. Further, we believe that some of the new clinical quality measures that CMS added to the proposed QRS measure set are highly problematic and should be deleted.

- **Third, to enhance the quality, utility, and clarity of the information to be collected, we urge CMS to lay out a glide path for incremental implementation of the QRS and transition to full implementation in 2017.** Considering the potentially exorbitant costs of an unnecessarily complex system, we recommend that the 2016 QRS include only administrative measures. Depending on CMS' re-estimate of the cost and collection of hybrid measures, at most hybrid measures should be display-only (i.e., only for display to CMS) until the cost burden of collecting these measures is accurately documented.

The next two sections provide detailed comments concerning (1) the accuracy of the estimated burden; and (2) the necessity and utility of the proposed information collection.

* * *

DETAILED COMMENTS ON THE ACCURACY OF THE ESTIMATED BURDEN OF COLLECTING INFORMATION FOR THE QRS

Issue. The cost estimates provided by CMS in the March 2014 *Supporting Statement – Quality Standards* of $117,424 to collect and report quality measures for QRS are significantly underestimated. Moreover, the proposed costs do not reflect the change of measures or increase in the total number of clinical quality measures in the final set. Based on feedback received from Blue Plans, estimates to collect and report quality measures for QRS range from $275,000 to over $800,000 per year. Estimates to collect and report data for the ESS range from $30,000 to $150,000 and estimates must include the vendor fees which may account for roughly 80% of expense.

	Total Estimated Costs for Claims Measures[1]	**Total Estimated Costs for Hybrid Measures[2]**	**Total Estimated Costs for Survey Measures[1]**
Plan A	$797,840		TBD
Plan B	$300,000	$400,000	$150,000
Plan C	$70,000	$200,000	$30,000
Plan D	$150,000	$216,000	$35,000

[1] May or may not include direct (e.g., internal staff oversight and management) and indirect costs (e.g., vendor fees).
[2] Includes cost spent requesting, tracking, obtaining, reviewing, and submitting medical records.

Plan E	$655,000	$155,040	TBD
Plan F	$275,000		$75,000
Plan G	$740,000		

Recommendation. CMS should revisit estimates of QHP issuer burden and make necessary adjustments to the timing of implementation of the QRS.

Rationale. There are a number of reasons why we believe the CMS estimates are inaccurate and need revising:

1) The cost for collecting and reporting medical record (i.e., hybrid) measures is quite substantial and includes costs of staff requesting, pursuing, and evaluating medical records, as well as copy service fees. In addition, the required sample of records, particularly for larger Plans, may be more on the order of 411 records with 5-10% oversample which is 20-30% higher than the 335 CMS estimated number of records.

2) There are costs associated with the new measures that are higher than the costs associated with those that were deleted. Plans do not currently collect and report medication adherence measures (e.g., Proportion of Days Covered measure). In addition, certain data such as pharmacy claims and behavioral health require contracting with vendors to properly report the requested measures. This challenge can be further exacerbated when attempting to obtain sensitive data from a vendor when there is a behavioral health "carve-out". The CMS estimates failed to incorporate these additional categories of expenses.

3) The timing of the submission of QRS measures may add further expenses. If the timeframe is not aligned with existing reporting periods, Plans, Plans will incur the costs associated with the establishment of a separate reporting process. Having a similar cycle to HEDIS will be helpful due to QHP activities that are on-going throughout the year such as planning, measurement (for hybrid measures, medical record retrieval), abstraction, audit and reporting.

4) The average medical record sample size for each hybrid measure is underestimated. The average medical record sample size of 335 does not account for the usual full sample size needed for the hybrid measures. Usual sample size for the hybrid measures included in the QRS measure set is 411 (up to 548 for diabetes measures) with a 5-10% over-sample. While the sample size of 335 might be reasonable for smaller health plans, larger health plans will need to have a larger sample. As this will be the first time these measure results are reported, it is anticipated that no health plans would be able to reduce their sample size based on the previous year's measure performance.

5) For QHPs accredited by entities other than NCQA, the NCQA HEDIS measures represent additional costs associated with purchasing software and licensing fees. In addition, third-party validation fees will be required for data collection, validation, and submission. As the vast majority of quality measures included in QRS are HEDIS® measures, this puts QHPs that are not accredited by NCQA at a disadvantage as they will incur these additional costs on top of the annual costs of collecting, validating, and reporting the data. As HEDIS®

measures are proprietary, it is not clear if these capital costs also include any licensing fees that could be incurred by QHPs that are accredited by a HHS-approved organization other than NCQA.

Issue. Because the measure specifications are still not finalized, the cost estimates above are remain highly uncertain.

Recommendation. Finalize QHP measure specifications as soon as possible so that QHPs will be able to allocate resources in timely manner.

Rationale. If the QRS measures have different specifications than HEDIS, then resources and timelines have great impacts to measurement and reporting. Extra time and resources are needed to program each measure, retrieve medical records for hybrid measures, and complete the audit process.

DETAILED COMMENTS ON THE NECESSITY AND UTILITY OF THE PROPOSED INFORMATION COLLECTION

Issue. The reliability of results for hybrid measures when applied to the health exchange population is problematic because of cost and methodological issues.

Recommendation. CMS should not use hybrid measures in the 2016 QRS measure set. CMS should only use hybrid measures as "display-only" for initial years and not calculated as part of the quality rating.

Rationale. Especially in the early years, QHPs are likely to face challenges in reliably reporting clinical metrics because of small sample sizes. This will be compounded by potentially significant population instability, posing particular barriers to measures requiring longitudinal data (e.g., two years of continuous enrollment). For example, many of the QRS measures apply to subpopulations (e.g. women age 16 – 24). Thus, substantial risk exists that the application of QRS measures to the exchange population may not produce valid, reliable, and useful results.

We are concerned that 2016 is too soon for reliable measure reporting. In general, it takes at least three years from the inception of a program until measures based on clinical data can be used for evaluation and public reporting: one-and-a-half years for initial, "new measure" year of data collection, consisting of a one-year period of accumulation of cases and six months for claims lags, data cleaning, audits, and analysis for data completeness and basic reliability; followed by a second year-and-a-half measurement period to determine year-to-year variation and to correct major data issues.

Administrative measures do not incur as much burden as the hybrid measures and can still provide useful quality information. However, this would require some changes to the proposed scoring methodology to ensure ratings could still be reliably calculated.

Issue. Many health plans lack access to the data that is required by certain measures within the proposed QRS measurement set. Even administrative measures that require access to behavioral health or pharmacy data are problematic because Plans lack access.

Recommendation.

1) CMS delete the following measures because of data/methodological problems:

- Appropriate Treatment for Children With Upper Respiratory Infection
- Proportion of Days Covered
- Human Papillomavirus Vaccination in Female Adolescents
- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

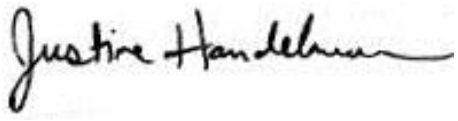
2) Moreover, the remaining new measure additions should be considered pending until CMS has redone its cost estimates.

Rationale. Measures that require mental health, pharmacy, dental, and other carve-out benefit data can be difficult for Plans to reliably obtain in a large enough sample size to collect and report these measures. For example, *Proportion of Days Covered* will be a problematic measure for Health Plans, especially since this measure is a Pharmacy Quality Alliance (PQA) measure that many Plans have never reported on and will be required to develop entirely new systems and processes to capture this measure. We also believe that auditors are not currently licensed for PQA measures. *Human Papillomavirus Vaccination in Female Adolescents* is still relatively new and remains somewhat controversial with variation in practice. Additionally, health plan results for this measure have not yet been published on Quality Compass, so plans have not been able to baseline and benchmark their performance. Finally, *Initiation and Engagement of Alcohol and Other Drug Dependence Treatment* is a new measure and it is difficult to identify the members to include in this measure, as well as to work with providers on this measure due to confidentiality issues.

* * *

We appreciate your consideration of our recommendations and comments. We look forward to continuing to work with HHS on QHP quality reporting and other implementation issues related to the ACA. If you have any questions or would like further information, please contact Joel Slackman at joel.slackman@bcbsa.com or (202) 626-8614.

Sincerely,



Justine Handelman
Vice President, Legislative and Regulatory Policy
Blue Cross and Blue Shield Association