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Dr. Donald M. Berwick
Administrator
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Dr. Berwick:

The Pharmacy Quality Alliance (PQA) appreciates the opportunity to comment on the **proposed rule for release of Medicare data for performance evaluation of providers and suppliers [CMS-5059-P]**. As you may know, PQA was established with the support of former CMS Administrator, Dr. Mark McClellan shortly after the implementation of the Medicare Part D Prescription Drug Benefit. It was his vision for the creation of this Alliance that led to the launch of PQA at a CMS Open Door Forum in April, 2006. Mark's continued participation on our Board has provided us with much valued input at various stages of our evolution as an Alliance.

Today, we are an alliance of over 60 member organizations, and we operate as a 501(c)3 organization. We have been fortunate to have Dr. Jeffrey Kelman serving on our Board of Directors as well as the input of the CMS staff to our discussions of pharmacy quality. PQA is pleased to provide input for the selection of performance measures for Medicare Part D and supports CMS efforts to enhance the quality and transparency of the Medicare drug benefit.

Overall, we believe that the proposed rules are a reasonable starting point for ensuring that the Medicare data are used in an appropriate manner for performance measurement. We would like to offer the following comments on specific aspects of the proposed rule.

<u>Qualified Entities</u>
We support requirements that would limit the release of data to entities that demonstrate the expertise to conduct appropriate analyses and who would have access to other data that would be necessary to perform robust assessment of the selected providers or organizations. However, we are concerned that the proposal to require entities to have at least 3 years experience in performance measurement is an unnecessary barrier to entry for new entities. We believe that the entity should be judged on the qualifications of the key staff and whether it possesses the infrastructure and resources to successfully carry out the performance analyses. Therefore, new entities could be considered by CMS if the key staff has experience in carrying out performance analyses at other entities in the past.

We are also concerned that the qualified entity would need to have the non-Medicare data in its possession before being approved by CMS. We think that a more reasonable requirement is for the applicant entity to have written agreements in place with the non-Medicare data suppliers to provide access to the data to be used in the performance assessment.

Some non-Medicare data suppliers (e.g., commercial health plans or pharmacy benefit managers) may only be willing to provide data after the applicant entity has been approved by CMS as a "qualified entity." Additionally, most performance assessment programs require regular updates of datasets to ensure that the performance reports on providers are based on the most recent data available. Thus, a requirement that the private-sector data are already stored at the applicant entity runs counter to the typical model for performance assessment. Therefore, we recommend that entities be considered for approval as long as they have the necessary agreements in place with non-Medicare providers of data.

With regards to the proposed requirement that the qualified entity have data from 2 or more non-Medicare sources, we suggest that the requirement NOT be based on the *number* of other sources but on whether the entity will have access to data that are necessary to carry out the proposed performance evaluation. It is possible that in some situations, it would be necessary to have 3-4 non-Medicare sources of data while in other unique situations it would be possible to conduct an appropriate performance evaluation with only Medicare data. Thus, we suggest that the applicant entities would need to indicate the nature of the performance evaluation that they intend to conduct and to demonstrate that they have access to a sufficient amount of non-Medicare data to allow an appropriate assessment within the targeted population.

Selection and Use of Performance Measures

We support the proposed allowance for use of performance measures that are not endorsed by the National Quality Forum (NQF) as long as another consensus-based entity has endorsed the measures. There are gaps in the current set of NQF-endorsed measures, so it is quite appropriate to create a mechanism for consideration of measures that are endorsed by entities other than NQF. We are concerned that the proposed alternative measures would be subject to a comment period since this will preclude the use of the alternative measure within the first year of the performance evaluation program. We suggest that if an alternative measure was already endorsed by a consensus-based organization (e.g., the Hospital Quality Alliance, Nursing Quality Alliance or Pharmacy Quality Alliance) that it would not be subject to the requirement of a public comment period.

We also support the proposed requirements related to submission of proposed reporting formats and templates prior to approval as a quality entity, but to also allow the qualified entity to make modifications to those reporting formats upon gaining experience with them. It will be important for CMS to make a timely decision on the modifications so that the performance reports are not significantly delayed.

Extraction and Dissemination of Data

We support the proposed rule regarding the type and amount of data that would be provided by CMS. We believe that only minimal technical support will be required by the qualified entities since only entities with experienced staff will be approved. Therefore, the fee can be kept to a minimal level and would not need to account for substantial technical support.

Regarding the three options that are being considered relative to the release of patient identifiers to the qualified entity, we strongly recommend option 1 wherein the qualified entity is provided access to a crosswalk file that allows access to the beneficiary identifiers IF the identification of the patient will be necessary to link to non-Medicare data for the same patient and facilitate the accurate calculation of the selected performance measures. Under this option, the qualified entity must have policies and procedures that appropriately limit the disclosure of patient identifiers to only the providers that request the patient identifiers for purposes of verifying the accuracy of the performance reports. It will also be important for the entity to attest to their ability to protect the privacy of the patient identifiable data.

Fees & Applications

The proposed fees for obtaining the CMS data would appear to limit access to entities that have substantial funding for their performance evaluation activities. We do acknowledge that CMS will have operational costs associated with the provision of data and the processing of applications; however, we believe that the fee should be based solely on the estimated cost for providing the data and should not contain the proposed additional fee that is based on the number of beneficiaries included in the data file. Since some of the entities that would be requesting data for performance evaluation are non-profit organizations, we hope that the fees are kept as low as possible so as to not prohibit non-profit organizations from participating in this program and to minimize the costs to the private sector for engaging in performance improvement.

A final concern is the proposal that CMS would only consider applications one time per year. We strongly encourage CMS to consider the establishment of quarterly deadlines for applications so as to not delay the implementation of new performance evaluation programs.

Thank you for the opportunity to comment on the proposed rule. We believe that the inclusion of Medicare data within non-governmental performance evaluation programs will be essential to the continued improvement of healthcare in the United States.

Kind regards,

Laura Cranston, RPh
Executive Director

Cc: PQA Board of Directors