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Comments on Proposed Rule, Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

Dear Dr. Berwick:

We appreciate the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) on Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, published in the Federal Register on July 15, 2011. The rule addresses a set of issues that are critical to building a functional marketplace through the Health Insurance Exchanges, and represents an important opportunity to make the operation of those Exchanges actuarially safe for insurance issuers and efficient for health insurance buyers.

Our comments focus on section 153.340—Data Collection Under Risk Adjustment—and respond to the Centers for Medicare & Medicaid Services' (CMS's) request for comment on its proposed approach, and on the potential advantages and disadvantages of alternative approaches. Effective risk adjustment is important for insurance markets to function well, particularly for higher-risk individuals, and must be performed in a manner that addresses the practical realities of aggregating increasingly detailed individual health care data, and that allows for the kind of flexibility that is required in the heterogeneous environment in which the Exchanges will be launched.

In particular, CMS proposes in section 153.340 that "the State, or HHS on behalf of the State, must collect risk-related data to determine individual risk scores that form the basis for risk adjustment." CMS describes this approach, on page 41940 of the Federal Register announcement, as "an intermediate State-level approach, in which issuers submit raw claims data sets to the State government, or the entity responsible for administering the risk adjustment process at the State level," and "a centralized approach in which issuers submit raw claims data sets to HHS," respectively. In so doing, CMS rejects "a distributed approach in which each issuer must…pass on self-determined individual risk scores and plan averages to the entity responsible for assessing risk adjustment charges and payments."

We believe that CMS should permit a distributed approach to support risk adjustment as an option as well, providing States flexibility to determine which approach might

work best for them**.** Our recommendation reflects the following key points:

- For a number of reasons, some States may prefer this approach. Offering this flexibility will also permit further opportunities for learning which method is best.
- There is rapidly accumulating evidence that distributed models can succeed, not only in the private sector but in the public sector as well, and offer some important advantages over methods involving a centralized data warehouse.
- Assuring data quality and consistency, and minimizing reporting burden, are not issues unique to distributed approaches. Indeed, our experience suggests that:
    - A distributed model has unique advantages in assuring data consistency and quality, because the data remain close to those who know it best and are thus best suited to assess and address any idiosyncrasies or anomalies.
    - A distributed model reduces administrative burden by leveraging existing and developing infrastructures, including those being established to support Exchanges, as well as quality improvement and other activities.
- A distributed model for risk adjustment helps assure protection of patient information and addresses concerns about the threats to privacy and security, because potentially identifiable information generally remains at the source rather than being stored in new, more centralized databases.

We review these points in more detail below, based on our experience with policies related to health care data analysis and our practical work on a variety of efforts addressing both public-private sector alignment on measurement and data aggregation across multiple payers. For example, our recent work on the High Value Health Care Project, which demonstrated how to consistently aggregate and link data using distributed data methods from multiple data owners including health plans, registry owners (e.g., American College of Cardiology), and others to measure performance.

Our work with the Quality Alliance Steering Committee (QASC), a multi-stakeholder collaborative supported by a diverse group of private and public stakeholders charged with identifying viable pathways to collecting and reporting on performance measures and improving care today. Our comments also reflect our interaction with FDA's Sentinel Initiative, which has already successfully piloted distributed-data methods for safety surveillance of medical products, as well as our work in advising HHS' Multipayer Claims Database project, which has taken a number of steps toward accommodating distributed-data methods.

Indeed, our work with the "Beacon" communities—where *summary-level* performance results are computed separately for Medicare and commercial health plan data and then aggregated at the community level—has demonstrated that both centralized and decentralized approaches can co-exist. Other community-based initiatives like New York

City's Health eHearts program have also successfully offered both centralized and decentralized approaches to data submission and aggregation,[1] adding an additional layer of flexibility for data holders which can be important for promoting participation.

Efforts like these have demonstrated how summary-level data from diverse sources can be combined to achieve a broad range of policy objectives, while addressing security concerns and the inevitable complex and often-subtle variations across different data system.

Some States may prefer a distributed approach. Offering this flexibility will also permit further opportunities for learning which method is best.

For a number of reasons, some states may prefer to pursue risk adjustment through distributed methods. The specific risk adjustment methodology may not be finalized for some time by HHS, perhaps not until a notice after the final rule. This will mean limited time for organizations to comply with the rule. As a result, especially in the initial years of the program, it will be very important for organizations to have an efficient way of both providing the needed data and providing needed plan-specific insights into applying the methodology effectively. A distributed approach, in which the plans are actively involved in assuring their data meet the requirements of the rule, is more likely to succeed with the tight timing for implementing risk adjustment than requiring the submission of data centrally that are unlikely to be comparable. It also means that CMS can concentrate more on outreach and coordination with the plans on meeting the technical specifications, rather than having to support the building of centralized, individual-level risk adjustment databases in every state (or multiple states and a federal fallback).

Offering the flexibility to pursue a distributed approach would also permit further opportunities for learning which method is best. Many experts would likely agree that, for both risk adjustment and other key activities where aggregation of individual health care data is required, the best solution in a rapidly evolving electronic data environment may not yet be clear. By allowing States the flexibility to implement the approach that each State feels will work best, CMS has the opportunity to learn more about which model or combination of models works best, and in what setting.

There is rapidly accumulating evidence that distributed models work and work well, not only in the private sector but in the public sector.

[1] Bridges to Excellence (2009). *Measuring What Matters: Electronically, Automatically, and (Somewhat) Painlessly.* http://www.rwjf.org/qualityequality/product.jsp?id=44907. See diagram on page 9.

HHS is already relying on distributed methods in a range of efforts to evaluate and improve care. For example, analytic approaches relying on distributed methods and standardized data queries:

- Are being implemented by the Food and Drug Administration to improve the post-marketing surveillance of pharmaceuticals through the Mini-Sentinel pilot, developed to inform FDA's Sentinel System for conducting active medical product safety surveillance. Through the pilot, FDA has established a distributed data system that consists of a coordinating center and various data partners that allow queries of electronic health information from nearly 100 million Americans, while keeping such data within their existing health care systems.

- Are fully operational at the Centers for Disease Control and Prevention (CDC), where they permit the CDC to monitor outbreaks of disease and—through the Vaccine Safety Network – near real-time vaccine surveillance on a weekly basis.

- Have been demonstrated to be feasible through the Observational Medical Outcomes Partnership (OMOP), a public-private partnership that researches, develops, and empirically evaluates methods for active surveillance. In particular, OMOP has demonstrated the feasibility of establishing a distributed data system to facilitate the development of a risk identification and analysis system.

- Are being implemented in communities participating in the Office of the National Coordinator for Health Information Technology's (ONC's) Beacon initiative, which is implementing methods to combine summary performance results computed from Medicare data with results from commercial health plans to allow those communities to monitor and improve care.

- Have supported research on the comparative effectiveness, safety, and quality of care through a multi-site distributed research network involving collaborators at Harvard Medical School, Harvard Pilgrim Health Care, Group Health Cooperative, Geisinger Health System, the National Center for Public Health Informatics, and others.[2]

Finally, our own work at the Engelberg Center, on a Data Aggregation Project—involving multiple collaborators and funded by the Robert Wood Johnson Foundation through their High Value Health Care Project—establishes clearly that a distributed model for data aggregation offers a feasible, reliable, and cost-effective

[2] http://journals.lww.com/lww-medicalcare/Fulltext/2010/06001/Distributed_Health_Data_Networks__A_Practical_and.9.aspx

approach to data aggregation for quality measurement across health insurance plans.[3]

Assuring data quality and consistency, and minimizing reporting burden, are not issues unique to distributed approaches. A distributed model does, as CMS points out, create the need for each data holder (in this case, insurance issuers) to reformat its own data to map correctly to the risk adjustment database. But this work by health plans on the validity of their own data has, in all of the data aggregation activities described here, turned out to be the most effective and most efficient way to address the need for data quality and consistency.

The proposed rule states that "there is reason to be concerned that some issuers would make errors in calculating individual risk scores and plan averages. Furthermore, we believe that the complicated nature of a distributed risk adjustment model may prove challenging for some issuers, especially smaller issuers and would thus require significant involvement by the State, or HHS on behalf of the State."

Such data quality issues, and the associated burden for addressing them, are challenges for either centralized or distributed approaches. So the question is, which approach can assure data quality at the lowest burden level.

While it is true that developing and applying a common data model would involve effort by health plans working in a distributed environment, CMS should not underestimate the nature, and level, of effort required to implement a centralized model for risk adjustment (whether truly centralized at the federal level, or centralized State-by-State). The challenge to States effecting risk adjustment across issuers is to create sufficient standardization across data submitted by those issuers; that is essential whether it is done centrally (by the federal government or by the States) or using a distributed approach. The challenge to doing so centrally has been noted by experts in all of the projects described here, as well as many projects in which data are aggregated centrally: the deep understanding of the data (and thus the ability to address variations in data through the standardization process) is found among the data holders, not by those who maintain the central repository. In a distributed model, the central staff are responsible for working with these experts to develop a feasible common data model and standard ways of querying (extracting summary information) using that model. Standardizing data elements—an essential requirement for functional risk adjustment—is best done by those who know the data best. The summary data that are submitted will reflect that model. In contrast, in a centralized model, the individual level data are unlikely to be consistent when they are submitted, and any anomalies that are found will require follow-up with the original data holders anyway. Data inconsistencies that are not obvious are likely to

[3] http://www.rwjf.org/files/research/72031physician.pdf

be missed. Thus, accomplishing the critical work of standardization is likely to be significantly more demanding and time-consuming using the centralized models.

A distributed data system requires the capacity to consistently apply methods across each of the data sources, and methods for doing so have been well developed.[4] Developing a common data model to standardize particular data elements across data sources can address this. Data holders that use a common data model can run standardized distributed protocols and programming codes, ensuring more comparable results than when custom code is written for each disparate data source.[5] Thus, data consistency and quality are enhanced under such an approach.

Auditing will certainly be required to ensure data quality. But this is true in centralized approaches as well. Indeed, the tasks for States are simplified if their requirements consist only of developing a common data model and summarization methods (with the technical support of the plans providing the data), and then auditing to assure compliance with those methods, rather than having to undertake similar tasks as well as having to manage a sensitive and increasingly complex individual-level database at the same time.

Moreover, on page 41040, the NPRM raises the important point that "a fully distributed approach would leverage existing infrastructures established to support Exchanges." As laid out in the NPRM for Establishment of Exchanges and Qualified Health Plans (QHPs) (CMS-9989-P), Insurance Exchanges will be required to fulfill a range of functions and services. In particular, an exchange must establish a QHP accreditation process to certify plans and plan sponsors as having met the minimum standards of quality and consumer protection required to participate in the exchange. QHP accreditation will require the establishment of data links between plan sponsors and the exchanges to enable plan reporting of QHP certification criteria such as network adequacy, quality standards, marketing practices, service area, and premium rate increases. The data infrastructure used for QHP certification could potentially be leveraged to enable a distributed model for risk adjustment. Indeed, as many experts on quality improvement as well as provider organizations have noted, the ideal data sources for quality measures are the data actually used in the delivery of care, because they are most likely to be accurate and they do not require additional after-the-fact administrative costs to produce. The same is true for risk adjustment. Moreover, the development of a distributed model for risk adjustment could encourage greater collaboration between plan sponsors and exchange officials, which would facilitate the formation of a more effective and comprehensive QHP accreditation process as well as more impactful quality measures.

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[4] Platt, R., Wilson, M., Chan AK., Benner J., Marchibroda J., and McClellan M., The New Sentinel Network – Improving the Evidence of Medical-Product Safety. *The New England Journal of Medicine*. Aug 13, 2009.

[5] Janet Woodcock, "Data and Infrastructure for Medical Product Surveillance," presentation at the Brookings Institution, Washington, DC, 02 Dec 2009.

Finally, the proposed rule suggests that distributed approaches would "require issuers to be able to respond to multiple queries to support other functions, such as data to recalibrate the Federally-certified risk adjustment model, reconciling cost-sharing reductions payments, verifying risk corridor submissions, or auditing cost-sharing reductions or reinsurance payments." Indeed, one of the advantages of distributed models is that they offer the possibility of creating a single data infrastructure that is capable of a number of different applications, which tends to be more efficient and less burdensome—both for the data holders as well as the central aggregators—than creating multiple single-purpose data sets.[6] [7] [8] Reducing the effort required by data holders to implement a study may, in turn, increase their willingness to participate in a variety of secondary uses of their data in light of a growing number of requests to data holders.

A distributed model for risk adjustment helps assure protection of patient information and addresses concerns about the threats to privacy and security, because potentially identifiable information generally remains at the source rather than being stored in new, more centralized databases.

Finally, as the proposed rule has recognized, distributed models offer a key advantage when it comes to protecting the privacy and security of personal health information. In a distributed approach, data owners—in this case, issuers of health insurance—use standardized programming code to calculate summary statistics about groups of patients.[9] These summary statistics then can be combined across issuers to provide comprehensive information about the quality or performance of a provider, group, hospital, or community. In particular, specific, individual-level data need not be shared, so that privacy and security concerns are mitigated significantly. As long as all of the participating data sources are using the same methods in consistent ways, all that is generally needed to calculate aggregated performance measures is the summary information on such patients. This approach is consistent with methods recently advocated by the President's Council on Advisors on Science

[6] The Engelberg Center for Health Care Reform. Making Enhanced Use of Health Information. http://www.brookings.edu/events/2010/0514_health_information.aspx.

[7] The Engelberg Center for Health Care Reform (2010). Using Information Technology to Support Better Health Care: One Infrastructure with Many Uses. http://www.brookings.edu/~/media/Files/events/2010/0514_health_information/FINAL%20issue%20brief%2051310.pdf

[8] Diamond CC, Mostashari F, Shirky C (2009). Collecting and Sharing Data for Population Health: A New Paradigm. *Health Affairs*. 28(2): 454-466.

[9] Brown JS, Holmes JH, Shah K, Hall K, Lazarus R, Platt R. Distributed health data networks: a practical and preferred approach to multi-institutional evaluations of comparative effectiveness, safety, and quality of care. Med Care. 2010; Jun;48(6 Suppl):S45-51.

and Technology, to take advantage of multiple rich data sources without pooling all data in any one place.[10]

We acknowledge that distributed data methods are not the only way to support risk adjustment using data from multiple data sources. We also acknowledge that much work remains to be done to assure that such distributed risk adjustment methods are functioning well. But many implementation challenges also await centralized approaches to risk adjustment.

Further, distributed methods have advantages: They promote standardization, comparability, and benchmarking throughout the health care system; they promote transparency and may foster collaborative approaches to address inevitable data limitations and problems; they minimize sharing individual beneficiary-level information (hence reduce both the risk, and the perceived threat, to beneficiary privacy and data security). Moreover, these methods can accommodate methodological innovation and improvement by systematically testing promising new approaches. Additional data elements, such as key clinical and demographic information not generally found in administrative datasets but which may be important to valid risk adjustment, can be tested, validated, and rapidly incorporated. For example, demographic and socio-economic factors like race and ethnicity can affect health care utilization and costs and are therefore valuable data points for risk adjustment. While this information is typically not captured in claims data, they are increasingly likely to be captured in electronic health records as a result of Stage 1 Meaningful Use requirements.[11] A distributed approach could more readily leverage this additional data as it becomes available. For all of these reasons, distributed methods are likely to be an important part of making performance measures widely and quickly available around the country.[12]

The proposed regulation offers an important opportunity to permit States to address the problem of risk adjustment in the way that best reflects their priorities and capabilities. It also offers an important opportunity for learning, at a time when the answers to challenging problems are not yet fully articulated. Allowing States to use distributed methods for risk adjustment is important to achieving those objectives; in particular, we believe that explicitly recognizing the potential value of distributed data methods can enhance the impact and address some of the key challenges in creating the Exchanges.

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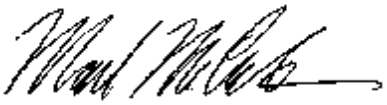
[10] President's Council of Advisors on Technology and Science. Report to the president: realizing the full potential of health information technology to improve healthcare for Americans; the path forward [Internet].Washington (DC): The Council;2010 Dec [cited 2011 Feb 14]. Available from: http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf

[11] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs: Electronic Health Records Incentive Program; Final Rule. http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf

[12] Roski J, McClellan M. Measuring Health Care Performance Now, Not Tomorrow: Essential Steps to Support Effective health Reform. Health Affairs. 2011; 30(4):682-689.

Thank you for considering our comments and recommendations on the NPRM on Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment. We look forward to providing further assistance to CMS in the further development and implementation of this important program.



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