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June 20, 2011

Dr. Donald M. Berwick  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: Comments on Medicare Program: Availability of Medicare Data for  
Performance Measurement (CMS-5059-P)

Dear Dr. Berwick,

Thank you for the opportunity to provide comment on the proposed rules for Medicare Data Sharing. As an All Payer Claims Database (APCD) the Wisconsin Health Information Organization (WHIO) is very interested in working with CMS to facilitate the release and use of the Medicare claims data.

WHIO has created one of the most comprehensive sources of health claims information available in the United States. The data and accompanying analytical tools are being made available to health care stakeholders as a resource to improve health care transparency, quality and efficiency.

The WHIO Health Analytics Exchange (HAE) functions as a data-driven marketplace that enables members to invest information and receive valuable reports analyzing health system and physician performance. For example, the HAE can be used to identify gaps in care for treatment of chronic conditions, costs per episode of care, population health, preventable hospital readmissions and variations in generic prescribing. Below are some of the features of WHIO's HAE:

- **An unprecedented volume of data:** The HAE contains an unprecedented volume and depth of data that spans multiple health care systems and settings including physician's offices, outpatient services, pharmacy claims, labs, radiology and hospitals. The data encompasses services provided by health systems across the state.
- **The ability to quantify performance over time:** The HAE holds a rolling 27 months of claims data that comprises the experiences of more than 3.7 million people and 233.5 million treatment services. A total of 21.5 million episodes of care are now found in the database and its scope will



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grow as new members join and contribute to the cooperative effort. An episode of care is defined as the series of treatments and follow-up related to a single medical event, such as a broken leg or heart surgery or the year-long care of a diabetic patient.

- **The power to study comparative performance:** The analytics available through the HAE allow individual physicians and group practices to compare their performance over time to that of their peers. The custom reports and independent querying capabilities help identify best practices, gaps in care and quality opportunities.
- **The scope to understand health care costs:** The current version of the database contains more than \$59 billion of health care expenditures and allows comparisons of those expenditures by region, county, ZIP code and medical system.
- **A new level of transparency and accountability:** Analyses of the data and reports from the HAE will level the playing field and create opportunities for dialogue among employers, insurers, providers and public policy-makers.

Due to the lack of Medicare data, the current claims data we collect represents the practice patterns of only a portion of the patient base for any provider or practice group. While the commercial and Medicaid claims data are significant, it is incomplete. The over-65 population in Wisconsin represents approximately 12 percent of all residents but a significantly larger portion of the health care claims.

The Medicare population is unique in its demographic, its health conditions, and in the way it seeks care. Providers who service Medicare patients have a legitimate concern with performance reports that do not include the care delivered to those patients; the reports they receive are an incomplete picture of their practice and may unfairly credit them with high (or low) performance scores. In addition, providers are unable to monitor their performance and the results of the changes in the delivery of care to Medicare patients.

We believe the proposed rule represents an important first step in filling the gaps of our data set with respect to providing access to Medicare data. However, we hope the final rule will contain several improvements upon the proposed rule that will facilitate access to the data and will complement our existing efforts with respect to other payers. Set forth below are our specific recommendations and comments on the proposed rule:



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WHIO applauds CMS for its intent to distribute Medicare data for the purpose of reporting on provider performance, however we suggest that the data also be made available for population based analytics and research initiatives that inform states of opportunities for quality and cost improvement in broad, directional ways.

The proposed rule would require advance notice and approval of specific measures and report format prior to use and distribution. This step is labor intensive and unnecessary. Advance commitment to use nationally approved or endorsed measures via a contractual Data Use Agreement will achieve the same result but retains the flexibility to allow the analytics to remain in sync with emerging national standards of performance or the changing of an organization's areas of focus (from diabetes to cardiology as an example).

Further, qualified entities (QEs) must submit understandable descriptions of measures so that consumers may assess performance. By requiring QE's adherence to nationally approved and endorsed measures for public reporting, the descriptions of the measures will be consistent across markets thus building common ground for consumers to communicate with physicians and other providers about their care. Development and adoption of this national vocabulary and measurement system will enhance clear communications among health care stakeholders and could be more swiftly and easily adapted to a national consumer education program.

The suggested cost of acquiring the data is prohibitive to nonprofit organizations. One way to mitigate this is to expressly permit the qualified entity to charge a subscription or report fee for analytics/data access that includes Medicare data to its members and/or subscribers. The current language of the proposed rule is unclear as to whether such a fee would be permitted.

It appears that a significant amount of the cost associated with acquiring the data is related to CMS audit and management of the data use. Qualified entities will have demonstrated their ability to have worked with HIPAA sensitive data in the past when aggregating commercial and Medicaid data. We believe that this expense can be minimized if CMS instead requires QEs to certify their HIPAA compliance during the application process and then contractually agree to remain in compliance going forward. CMS could then perform random audits to ensure compliance.

Finally, it would seem that data extraction costs (assuming the formats are standard) are heavily up front/ one time loaded. If these costs were pro-rated across all QE's and over three years it could bring costs into an affordable range.

Other specific comments/suggestions include:



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Eligibility Criteria (Preamble starting at 6)

The expected functions of the QE are found at pages 7-9 of the preamble. Of concern is the proposed rule's requirement that applicants have "demonstrated expertise and sustained experience...calculating performance measures for a period of at least three years," including three years of profiling providers of services and suppliers. (Preamble at 9). The proposed rule, sec. 401.703(a)(1)(i), requires three or more years of "accurately calculating quality, efficiency, effectiveness, and resource use measures from claims data" and seems to suggest that organizations should have been making performance reports available, for at least three years, to "consumers, providers...health plans, researchers, and other stakeholders...." Sec. 401.703(a)(1)(v).

The WHIO business model is such that all data sources are combined into a patient de-identified data utility and members and subscribers produce analytics using that data and a uniform reporting tool. In combination, the WHIO data base and reporting tool are referred to as the HAE. The WHIO HAE is capable of these analyses and subscribers can and do use the HAE to run such reports, and have been doing so for three years plus. In addition, existing WHIO/Optum quality control functions exist to support the functionality expected by the rule.

We request clarification that organizations like WHIO will be allowed to demonstrate sustained capability of the data set, including data use requirements, appeal processes, etc., with these expectations, even if some of the specific functions have been performed by others under contract for the required timeframe.

Identifying Measures in Advance (Preamble at 13)

The proposed rule at sec. 401.704 requires applicant organizations to, as part of the application for the Medicare data, "[s]ubmit to CMS a list of all measures it intends to calculate and report...and the methods of creating and disseminating reports." Prototype reports must also be submitted with the application. Measures must be chosen from current National Quality Forum measures; there is also a lengthy process for suggesting alternative measures. While the goal of reporting only valid, reliable measures is laudable, the process of identifying measures and report formats up front for a three year approval period seems unnecessary and limiting. Our desired focus could be expected to change over a three year time frame; the utility of certain measures to data subscribers would also change. While the proposed rule does contain instructions for updating proposed measures and report formats (sec. 401.706), we recommend qualified entities be allowed to commit to using only NQF measures under a contractual Data Use Agreement rather than being required to identify specific measures up front.



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Data Periods (Preamble at 31)

The utility of the analytics produced from an all payer claims data set (APCD) is directly related to the timeliness or currency of the measurement and the sample size of the data that was used to produce it. Ideally this means that Medicare data will be linked with commercial and Medicaid data of the same time period and that the time period is as recent as possible. Notably, the WHIO data set is refreshed every six months and includes claims that are 90 days or more in the past. The rule indicates that Medicare data will be distributed annually and released 15 months following the close of a calendar year. Per the example in the preamble, an entity approved in 2012 would get data for CY 2008, 2009, and 2010. In addition, Medicare data would be made available annually, whereas a new DMV is released every six months. We urge CMS to consider a significantly more timely release (monthly or quarterly are preferred but semiannually at a minimum) of the Medicare data to improve its value and allow the publication of performance reports that will truly drive changes in delivery/increased value in healthcare.

Nationwide Data (Preamble at 32)

It appears that a state will be the default geographic area for release of data, but CMS is willing to make nationwide data available. WHIO (and potentially the APCD Council and/or NAHDO) seek specific language that supports the release of national Medicare data to any QE or association of entities that can produce a nationwide (or super regional subset) commercial data set.

Further, there is some concern that by defining regions or sub-regions that rural clinics might not be included in the data. In order to avoid misleading and incomplete analytics, we encourage CMS to ensure that these rural clinics be included in the data.

Timeliness and Physician Preview process

In order for the analytics produced to be meaningful and therefore actionable for the consumer and the provider they must be timely – not older than six months. The process to release the data for approval in such a short time frame requires that any audits occur upfront during the process of data creation rather than after the fact. Therefore, we suggest that if HHS/CMS has 1) approved the audit of claims (which is already done by the administrators); 2) approved and audited the data extraction and aggregation processes of the QE as part of the qualification process; and 3) approved and audited the methods of reporting and analysis (also as part of the QE qualification process), further review by the physician is unnecessary.



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### QE Subcontracting

It is unclear whether a QE must be totally self contained – that is, perform all of the data aggregation, reporting methodology and analytics internally – or if it is allowable for a QE to subcontract with a third party for its technology/data/analytics management. Certainly the burden of compliance with all aspects of the rule would fall to the QE but it is likely that at least some of the processes would be handled under contract with a specialty vendor. WHIO seeks clarification as to whether this is permissible.

### Business Model and Costs (Preamble starting at 33)

QEs must demonstrate how they will cover the costs of receiving the data, estimated by CMS to be \$200,000 for 2.5 million beneficiaries. If there are roughly 900,000 people enrolled in Medicare in Wisconsin today, WHIO's cost could be expected to be somewhere between \$80,000 and \$100,000 for our share of Medicare claims. QEs would need to pay the fee annually; CMS says the costs would be "lower" after the first year.

CMS seeks comment on QEs ability to cover these costs. We believe that our ability to cover these costs is dependent upon our ability to charge customers for the data. However, the proposed rule does not address whether this would be permitted. We seek clarification as to whether a QE may include such a charge in its subscription charges.

CMS has also estimated ongoing costs of compliance with the proposed rule, starting at page 57 of the Preamble. Note that the initial application process is expected to take 500 hours of work, the reapplication process (every three years) 120 hours, and the annual report 150 hours. This is a significant time investment and contributes to high program costs. We believe that the application and compliance process must be simplified so as to reduce these costs and the burden on QEs. We encourage CMS to consider ways in which the process could build on other audit processes that are part of existing data management and aggregation activities so that the increase in work is less burdensome and costly.

### Data Use Agreement (Preamble at 37)

The rule proposes to use the *current* Medicare DUA (apparently designed for limited, one-off research type requests) for a new, and much broader, distribution and use of Medicare data.

The current Medicare DUA contains language that *could* conflict with the WHIO DUA and business model, e.g. "The User agrees not to disclose, use or reuse the data...except as specified in an Attachment to this Agreement..." (Medicare DUA



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at 2.) It is essential to WHIO to integrate Medicare data with Commercial and Medicaid data in the HAE and to manage the access and use of the data under our standard operating procedures and DUA provisions. It is unclear whether the proposed rule as drafted and the existing Medicare DUA would permit this.

The Medicare DUA goes on to say that “within the User organization and the organizations of its agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this section....” (Medicare DUA at 2.) This seems inconsistent with the underlying purpose of making Medicare data available for quality reporting purposes.

In addition, the Medicare DUA requires an agreed-upon data destruction date. While this would not necessarily be a barrier to participation it might prohibit certain longitudinal studies and should be considered in that regard.

Names (Preamble at 38)

There are three options for release of names/crosswalk tables: 1) up front, 2) on a transactional, per-request basis by the QE, and 3) on a transactional, per-request basis by a provider. CMS indicates that it prefers option two (Preamble at 39). However, without the names/cross walk information up front we will be unable to match the Medicare records with the commercial or Medicaid records. As a result we would lose the ability to create a single patient eligibility record and track all claims (commercial, Medicaid and Medicare) to it. This lack of matching would result in multiple records for a single patient and distort analytics for providers – increasing the ‘N’ is one of the biggest reasons for release of the Medicare data. All QE’s will have previously demonstrated their ability to be compliant with HIPAA privacy and security provisions (or would not have been able to aggregate data from multiple sources) so option 1 makes most sense and delivers greatest value.

Application Process (Preamble at 53)

CMS proposes taking applications once per year, in the first calendar quarter. If the requirement to select measures and report format for approval remain in place then we recommend that two application periods be set up in year 1: end of Q1 and end of Q3, to allow for organizations like WHIO to do planning as to which quality measures we would propose to report.



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We thank you for your consideration of our comments. Please do not hesitate to contact us if you have any questions.

Sincerely,

Julie Bartels  
CEO

Wisconsin Health Information Organization