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RE: Proposed Rule on Availability of Medicare Data for Performance Measurement; 76 Federal Register 33566-33588 (June 8, 2011)

Attention: CMS-5059-P

Dear Dr. Berwick:

The Network for Regional Healthcare Improvement (NRHI) appreciates the opportunity to submit comments on the Proposed Rule issued on June 8 regarding the release and use of Medicare claims data to measure performance, and to respond to a number of the specific issues you raised in the Preamble to the Proposed Rule.

# I. OVERVIEW

As you know, NRHI is the national association of Regional Health Improvement Collaboratives – non-profit, multi-stakeholder, community-based organizations that are working to improve the quality and reduce the costs of health care in dozens of metropolitan regions and states across the country. Many NRHI members are also designated as Chartered Value Exchanges (CVEs) by HHS and AHRQ.

Regional Health Improvement Collaboratives have the most extensive experience in the nation in successfully implementing performance measurement and public reporting efforts for a wide range of measures and for patients associated with multiple payers, and in ensuring the reports are used to actually improve the quality of care in a community. A number of our members have been collecting and publicly disseminating measures of the quality of healthcare services in their communities for multiple years, and a growing

number of our members also measure and report on patient experience and the cost of care.

Unfortunately, the ability of Regional Health Improvement Collaboratives to identify and address opportunities to improve quality and reduce cost has been impeded because claims data on the care delivered to Medicare beneficiaries have not been available. Healthcare providers and suppliers are interested in using quality measurement to improve the quality of care for *all* of their patients, not just those covered by a particular type of health insurance. Patients also want to know that quality measures reflect the kind of care they will likely receive. However, for those communities which rely on claims data for quality measurement, the lack of Medicare claims data means that, in many cases, the quality measures their Regional Health Improvement Collaboratives can generate have to be derived from data on fewer patients than would be desirable or necessary for reliability, and in most cases, it means that the quality and cost of care for senior citizens cannot be accurately measured at all, and that disparities in care between seniors and others cannot be identified. For those Collaboratives which are working to measure and report on the cost of care delivered to citizens in their community, access to claims data is essential, and the lack of Medicare claims data means Collaboratives cannot accurately measure the cost of care delivered to Medicare beneficiaries or differences in the costs for Medicare beneficiaries and other patients.

Consequently, we strongly supported Section 10332 of the Patient Protection and Affordable Care Act which authorizes release of Medicare claims data to organizations such as Regional Health Improvement Collaboratives, and last September, we provided CMS with detailed recommendations on how to successfully implement Section 10332.

Many Regional Health Improvement Collaboratives intend to apply to become qualified entities under the provisions of Section 10332. Indeed, the Regulatory Impact Analysis in Section IV.B.1. of the Proposed Rule to implement Section 10332 (76 FR 33582) acknowledges that Regional Health Improvement Collaboratives will represent most of the organizations that can serve as Qualified Entities. However, <u>in a number of areas, the requirements in the Proposed Rule could either preclude participation of Regional Health Improvement Collaboratives entirely or make it extremely difficult for them to do so. These requirements are inconsistent with what we believe was the intent of Congress – to ensure that Medicare claims data can be used by as many communities as possible to help improve the quality of care for Medicare beneficiaries and thereby to also help control costs in the Medicare program.</u>

Our comments below identify aspects of the Proposed Rule that we believe would impose unreasonable or unnecessary restrictions or burdens on Regional Health Improvement Collaboratives in obtaining Medicare claims data for quality measurement and reporting, as well as our recommended remedies.

# II. ELIGIBILITY CRITERIA FOR QUALIFIED ENTITIES (§401.703)

## A. Length of Experience in Measurement and Reporting

§401.703(a) of the Proposed Rule requires qualified entities to have three or more years of experience in fifteen different areas, including combining claims data from multiple payers, publicly reporting data, etc. Although we agree that Medicare data should only be released to organizations which have the appropriate skills to manage it, we believe that requiring three years of experience in *all* of the areas described is inappropriate and undesirable. For example, many Regional Health Improvement Collaboratives have started their measurement and reporting programs by calculating quality measures and distributing them privately to physicians or other providers for a year or more, and then, after any problems with the accuracy of the data or the reliability of the measures have been resolved, the Collaborative will begin public reporting. Some Regional Health Improvement Collaboratives have successful programs to measure and report on the quality of healthcare using data drawn from electronic health records or manual abstractions of medical records, and are now seeking to expand to measures based on claims data. In such cases, a Collaborative might have three or more years of experience in many of the areas described in §401.703(a), but not all of them.

Moreover, requiring qualified entities to have three years of experience in handling and publicly reporting claims data will significant delay the ability of new Regional Health Improvement Collaboratives (or existing Collaboratives that have not been conducting quality measurement) to implement a broad-based quality measurement program. Although Section I of the Preamble states that CMS believes "the sharing of Medicare data with qualified entities through this program and the resulting reports produced by qualified entities would be an important driver of improving quality and reducing costs in Medicare, as well as for the healthcare system in general," the Proposed Rule is essentially forcing any community which has not been engaged in a quality measurement and reporting program to wait three years before it can use Medicare data to help improve the quality of care in that community. The need to improve the quality and reduce the cost of healthcare is too urgent to justify such a long delay.

Section II.A.2.a. of the Preamble (76 FR 33567) states that you "propose to consider applicants with fewer years of experience in handling claims data and calculating performance measures…if the applicant has sufficient experience in the other areas described above." We strongly support this type of flexibility; however, this discretion is not explicit in the wording of the Proposed Rule. We recommend that no minimum number of years of experience be specified in the regulation, and that CMS retain the discretion to approve qualified entities that have recently developed the necessary expertise to effectively utilize Medicare claims data.

**We recommend that §401.703(a) be revised to read as follows:**

> **(a) *Eligibility criteria:* To be eligible to apply to receive data as a qualified entity under this section, an applicant generally must demonstrate expertise and ~~sustained~~ experience~~, defined as three or more years,~~ to the Secretary's satisfaction in the following three areas…**

## B. Source of Experience

We believe that an important mechanism for increasing the number of communities with multi-payer quality measurement and reporting programs is to enable and encourage communities to contract for claims processing and analysis services from the organizations which manage such programs in other communities or with one or more of the firms which provide claims processing and analysis services to those organizations. In other words, communities can jumpstart the formation of new qualified entities by sharing the expertise and experience of existing qualified entities.

We urge that the wording of the Proposed Rule make clear that a qualified entity can "demonstrate expertise and sustained experience" in the specified areas through contracting with another organization which has developed expertise and experience in those areas from measurement and reporting efforts in another community. To do this, **we recommend adding the following subsection (b) to §401.703:**

> **(b) ~~[Reserved]~~ *Source of expertise and experience:* An applicant may demonstrate expertise and experience in any or all of the areas described in subsection (a) of this section either (1) through activities it has conducted directly through its own staff, (2) through a contract or partnership with a qualified entity in a different geographic area that has experience and expertise with the same types of data and measures that the applicant proposes to use, or (3) through a contract for services with one or more organizations or businesses that provide similar services to a qualified entity in a different geographic area.**

## C. Types of Measurement in Which Experience is Required

The Proposed Rule would require a qualified entity to have experience in "accurately calculating quality, efficiency, effectiveness, and resource use measures from claims data." This wording implies that a qualified entity must have experience with *all* of these types of measures in order to receive and use Medicare data for *any* of these measures. This is unnecessarily and inappropriately restrictive, particularly since only a small number of organizations are currently calculating and reporting measures of "efficiency," "effectiveness," or "resource use" and there are few measures that have been endorsed by the National Quality Forum that could be characterized as measures of efficiency, effectiveness, or resource use. Regional Health Improvement Collaboratives and other organizations that are currently using claims data solely for

quality measurement and that wish to include Medicare data should be permitted to do so without being required to have experience with or to use other types of measures. Since CMS has reserved the right to approve which measures a qualified entity can use Medicare claims data for, it will still have the ability to control what qualified entities with different types of experience do with the data they receive.

**We recommend that §401.703(a)(1)(i) be revised to read as follows:**

> **(i) Accurately calculating quality, efficiency, effectiveness, ~~and~~ or resource use measures from claims data, including:**

## D. Experience in Using Risk Adjustment Methods

The Proposed Rule would require a qualified entity to have expertise and experience in "using methods for risk-adjustment to account for variation in both case-mix and severity among providers of services and suppliers." However, many of the quality measures being reported today by Regional Health Improvement Collaboratives are not "risk adjusted," nor should they be; these measures are defined in terms of a specific patient population which should receive a particular care process or achieve a particular outcome all of the time (or avoid a particular event or outcome all of the time). Similar to the point made in the previous section, Regional Health Improvement Collaboratives and other organizations that are currently using claims data solely to generate quality measures that do not require risk adjustment should be permitted to include Medicare data without the need to demonstrate experience or expertise in risk adjustment methods.

**We recommend that §401.703(a)(1)(i)(C) be revised to read as follows:**

> **(C) Using methods for risk-adjustment where appropriate to account for variation in both case-mix and severity among providers of services and suppliers.**

## E. Business Model for Measurement and Reporting

The Proposed Rule would require that qualified entities demonstrate expertise and sustained experience in "a business model that would cover the costs of performing the required functions, including the fee for the data." This wording could be interpreted to mean that an applicant would need to already be generating the revenues necessary to carry out additional functions under the regulation and to purchase the data from CMS, even though the qualified entity's ability to generate those revenues could be conditional on whether it can obtain the data from Medicare.

In addition, it is highly likely that any business model will change over time, particularly over the next several years with the dramatic changes that are taking place in the structure of healthcare providers, suppliers, and payers. Consequently, the *most* that should be expected of any qualified entity is to have a *plan* for how to cover the costs of required functions, and CMS should not in any way limit the ability of a qualified

entity to adapt that plan to changing circumstances. Since CMS is requiring that data fees be paid in advance and that Medicare claims data can only be used for approved purposes, it is not necessary for CMS to involve itself in the finances of qualified entities.

Finally, a qualified entity's ability to generate funds to support purchase of data from CMS will depend heavily on the amount that CMS charges for the data (which we address in more detail in Section IV.C below), CMS's willingness to allow the data to be used in ways that support a community's needs (which we describe in more detail in Section IV), the timeliness and frequency of the data that are provided (which we discuss in Section IV.E below), and the timeliness of CMS's response to applications and requests from qualified entities (which we discuss in several subsequent sections of this letter). We urge CMS to work as a partner with qualified entities, so that qualified entities can structure a successful business model for using the data in a way that improves the quality of care for Medicare beneficiaries and helps control the cost of services for the Medicare program.

**We recommend that §401.703(a)(1)(iii) be deleted entirely, or if it must be retained, that it be revised to read as follows:**

> **(iii) A plan for a business model that ~~would~~ is projected to cover the costs of performing the required functions, including the fee for the data.**

## F. Experience in Combining Claims Data From Multiple Payers

The Proposed Rule would require that qualified entities have both expertise and experience in "successfully combining claims data from different payers to calculate performance reports." In Section II.A.2.b. of the Preamble to the Proposed Rule (76 FR 33568), you specifically requested comments on whether to require that qualified entities have (a) a minimum amount of claims data from a non-Medicare source, and (b) claims data from two or more other sources. You also expressed concern as to whether measurement based on only one other source of claims data besides Medicare would "represent enough of a provider of services' or supplier's patient population to provide meaningful data that would help performance."

We urge you not to require that an applicant have any minimum number or size of other claims data sources in order to be a qualified entity. The number and types of claims data needed to generate reliable measures depends heavily on the specific measures being used, the patient populations to which measures apply, the specific providers being measured and the types of patients they care for, and the number and types of healthcare payers in the local community. In communities where a single health plan dominates the commercial insurance market, the claims data from that single health plan and Medicare would likely be sufficient to generate statistically valid measures, and there would be no need to require a qualified entity to have claims data from additional payers to ensure statistically valid measures. Indeed, in some cases,

Medicare claims data alone can and should be used to generate measures that apply only to senior citizens or Medicare patients. In other communities where many different health plans share the market, claims data from two or even three commercial health plans might be too little to allow statistically valid measures to be generated. Consequently, CMS should simply require that qualified entities publish measures that are statistically valid, not attempt to specify in advance how much data they must have in order to do so.

We also urge you to modify the language of the Proposed Rule requiring that qualified entities have experience in "successfully combining claims data from different payers." This would, as a practical matter, require qualified entities to have access to claims data from two or more other payers. As noted in the previous paragraph, this may not be necessary to produce statistically valid measures, and it would be inappropriate to prevent qualified entities from generating and publishing valid measures simply because smaller payers refuse to contribute their claims data.

Moreover, this wording of the Proposed Rule also implies that qualified entities must be using non-Medicare claims data to generate measures prior to applying for access to Medicare claims data. This is far more stringent than what the law requires. Section 1874(e)(4)(B)(iii) of the Social Security Act (added by Section 10332 of the Affordable Care Act) merely requires that qualified entities "include data made available under this subsection with claims data from sources other than claims data under this title in the evaluation of performance;" it does not require that they already have such data. In fact, in some cases, the lack of access to Medicare data may be a major reason why a community has not pursued the creation of a multi-payer claims-based quality measurement and reporting system. For example, if a community has only one large commercial payer or if a high proportion of the residents are Medicare beneficiaries, there may be little value in pursuing a multi-payer claims-based measurement and reporting system if Medicare is not included. Making the provision of Medicare data contingent on a community already having a multi-payer claims-based measurement and reporting program may create a Catch-22 situation in which some communities could never qualify to receive Medicare data.

**We recommend that §401.703(a)(1)(iii) be revised to read as follows:**

> **(iii) ~~Successfully combining claims data from different payers to~~ The ability to access claims data from at least one other payer and to use those data for the purpose of calculate~~e~~ing performance reports.**

## G. Aggregation Level for Reporting

The Proposed Rule would require a qualified entity to have expertise and experience in "making performance report information available to the public in aggregate form, that is, at the provider of services or supplier level." It seems clear that the purpose of this provision was to ensure that performance measures are reported publicly, but not at the individual patient level. However, because the Proposed Rule

uses the definition of "supplier" from Section 1861(d) of the Social Security Act (which defines a supplier as "a physician or other practitioner, a facility, or other entity"), it may inadvertently be requiring reporting that is statistically invalid.

In many cases, an individual physician or other practitioner does not have enough patients with a particular condition, or does not perform a procedure frequently enough, to enable the quality or efficiency of that physician's or practitioner's performance to be reliably measured or to be compared to that of other physicians or practitioners. Consequently, in many cases, Regional Health Improvement Collaboratives only publicly report certain measures aggregated at the physician practice or group level, not for individual physicians or other practitioners, although individual physicians can receive their own quality measures privately. The wording of the Proposed Rule, however, could potentially be interpreted as requiring applicants to do *all* of their public reporting at the individual physician level in order to be designated as qualified entities regardless of whether such reporting would be statistically valid. This would be inappropriate.

**We recommend that §401.703(a)(1)(viii) be revised to read as follows:**

> **(viii) Accurately preparing performance reports on providers of services and suppliers and making statistically valid performance report information available to the public in aggregate form, that is, ~~at the~~ for providers of services ~~or~~, suppliers, or groups of suppliers ~~level~~.**

## H. Types of Organizations Eligible to Be Qualified Entities

The Proposed Rule is silent on the types of organizations which can apply to become qualified entities. Although we do not believe that CMS should attempt to impose detailed standards on the organizational structure of qualified entities, we are concerned that in certain circumstances, organizations could pursue becoming qualified entities to impede access to quality and cost measures, rather than to facilitate access. Consequently, we recommend that qualified entities be limited to either non-profit, multi-stakeholder organizations or government agencies.

**To implement this, we recommend that a new subsection §401.703(c) be added that reads as follows:**

> **(c) *Organizational structure.* In order to be approved as a qualified entity, an applicant must be either (1) a non-profit corporation with a governing board that includes representatives of providers, suppliers, payers (e.g., health plans or state Medicaid agencies), purchasers (e.g., employers in the community), and consumers, or (2) a state or local government agency.**

## I. Number of Qualified Entities in the Same Region

In Section II.G. of the Preamble to the Proposed Rule (76 FR 33579), you solicit comment on the implications of providers of services and suppliers receiving reports from multiple qualified entities and whether CMS should limit the number of qualified entities that are approved for a particular region.

Although we believe it is desirable that there be coordination among all measurement and reporting efforts in a community in order to increase the likelihood that citizens and patients will be able to find, understand, and effectively use the information, we believe that individual communities should decide how many measurement and reporting programs they need and how to best coordinate them. In a number of communities, for example, measures of the quality of care for physicians are being collected and reported by one entity and measures of the quality of care for hospitals are being reported by a separate entity. We urge CMS not to attempt to mandate coordination or to limit the number of potential measurement and reporting entities in a community.

# III. OPERATING AND GOVERNANCE REQUIREMENTS (§401.704)

The many requirements included in §401.704 of the Proposed Rule, when combined with the large number of additional requirements in §401.703 and other sections, will be quite burdensome for organizations seeking to become qualified entities. The Regulatory Impact Analysis in Section IV of the Preamble to the Proposed Rule (76 FR 33581-33585) estimates that 500 hours of time will be required to prepare an application, at an estimated cost of $22,733 per applicant, not including the cost of purchasing the data itself if the application is approved. The burdensome requirements in the regulation could have the unintended consequence of discouraging communities from applying and thereby reduce the number of communities using Medicare data to support quality measurement programs.

**We urge that CMS do everything possible to simplify the application process in order to reduce costs for applicants and to encourage broad use of Medicare claims data for quality measurement and reporting.**

For example, §401.704(a) requires a qualified entity to submit detailed information about each of the measures it proposes to use, including measure specifications and other information, even for “standard measures” for which the specifications are already known to CMS. This requirement could be simplified, thereby reducing costs for both the qualified entity and CMS.

# IV. APPLICATION PROCESS AND REQUIREMENTS (§401.705)

## A. Deadline for Applications

The Proposed Rule requires that applications to serve as qualified entities "must be submitted by March 31, 2012 and by the close of the first quarter of the calendar year each year thereafter." We believe it is inappropriate and undesirable for CMS to limit applications to a single date each year. The extensive application requirements imposed in the regulation will take considerable time and effort for organizations to fulfill, and if an organization cannot complete an application by March 31, it is unreasonable to make it wait another 12 months to apply and thereby to delay by 12 months or more the organization's ability to use Medicare data for measurement purposes.

Since these are not competitive applications – CMS could potentially approve qualified entities in every metropolitan area or hospital referral region in the country – there is no reason to have a single deadline. Moreover, despite the assertion in Section II.G of the Preamble to the Proposed Rule (76 FR 33580) that a rolling application process would impose a greater burden on CMS, we believe that having all applications coming in at the exact same time will make it difficult for CMS to dedicate enough staff resources to process those applications in a timely fashion, thereby leading to greater delays in responding than if the applications were spread out over a longer period of time.

Also, in Section II.G of the Preamble to the Proposed Rule (76 FR 33580) you indicate that you are planning to make applications for participation available on the CMS website beginning January 1, 2012. Since the provision of the Affordable Care Act authorizing the data release takes effect on January 1, 2012, we urge you to do everything possible to begin releasing data as close to that date as possible, including making applications available before the end of 2011.

Finally, we believe it is inappropriate for CMS to impose extensive requirements on applicants but provide no assurance of timely response. The need to expand the use and robustness of quality measurement efforts is urgent, and requires prompt action at both the community level and at CMS. We urge CMS to commit itself to respond promptly to all applications.

**We recommend that §401.705(a) be revised to read as follows:**

> **(a) *Application Deadline.* Qualified entity applications ~~must~~ may be submitted ~~by March 31, 2012 and by the close of the first quarter of the calendar year each year thereafter~~ at any time on or after November 1, 2011. CMS will either approve or reject the application within 60 days following receipt of the application.**

## B. Duration of Approval

We believe it is unnecessary and inappropriate for CMS to require a qualified entity to reapply after three years. The regulations include detailed requirements as to how organizations must use data, detailed requirements for reporting to and monitoring by CMS, requirements that qualified entities seek approval in advance for changes in measures and reporting methods, and authorization for CMS to terminate agreements with a qualified entity if there are problems with the way it is using data. Requiring qualified entities to reapply after three years achieves nothing other than increasing the administrative burden on CMS and on the qualified entity, and no rationale for this is given in the Preamble to the Proposed Rule, so we urge that this requirement be dropped.

**We recommend that §401.705(c) and §401.705(f) be revised to read as follows:**

**(a) *Duration of approval.* Once its application is approved, t~~T~~he entity would be permitted to participate as a qualified entity ~~for a period of three years from the date of notification of application approval by CMS. The qualified entity must~~ indefinitely, as long as it abides by all CMS regulations and instructions for this program. ~~If the qualified entity wishes to continue performing the tasks under this subpart after the three-year approval period, the entity may re-apply for qualified entity status following the procedures set forth below.~~**

**(f) *Reapplication.* Qualified entities will continue to receive Medicare claims data as long as they remain in good standing ~~may re-apply for qualified entity status~~. A qualified entity would be considered in good standing if it has had no violations of the requirements of the program or if the qualified entity is addressing any past deficiencies either on its own or through the implementation of a corrective action plan. If an organization loses its status as a qualified entity due to violations, it may reapply by~~To reapply a qualified entity would need to~~ submitting to CMS documentation of any changes to what was included in their original application and how the violations have been corrected. ~~Reapplicants would need to submit this documentation at least 6 months before the end of their three year approval period and would be able to continue to serve as qualified entities until the re-application is either approved or denied by CMS. If the re-application is denied, CMS would terminate its relationship with the qualified entity.~~**

## C. Cost of Data

Section 1874(e)(4)(A) of the Social Security Act (added by Section 10332 of the Affordable Care Act) requires that CMS charge a "fee equal to the cost of making such data available," and §401.705(e) of the Proposed Rule adopts this same language. We are very concerned about the way that CMS is proposing to calculate the cost of "making such data available."

In Section II.C.3 of the Preamble to the Proposed Rule (76 FR 33574), you estimate that the direct cost of providing three years of data for 2.5 million beneficiaries would be approximately $75,000. Since most Regional Health Improvement Collaboratives serve regions with 500,000 to 750,000 Medicare beneficiaries or fewer, this presumably means that the cost of generating data for them would be about $5,000 - $7,500 per year. (If three years of data cost $75,000, then presumably one year of data would cost one-third as much, or $25,000, and if data for 2.5 million beneficiaries would cost $25,000, then data for 500,000-750,000 beneficiaries would presumably cost 20-30% as much, or $5,000 - $7,500.) This would be affordable for most Regional Health Improvement Collaboratives. We believe that since this cost estimate was based on one-time data generation for research entities, the costs could be even lower if CMS generates all of the data for all qualified entities at the same time.

However, in the Preamble, you also indicate that you plan to "interpret the cost of making the data available broadly, to include the cost of providing …technical assistance… the cost of processing qualified entities' applications, and the costs of monitoring qualified entities to ensure appropriate use of the data and appropriate adherence to data privacy and security standards." You estimate that in addition to the cost of generating the actual data, the "cost of processing applications and data requests, providing technical assistance, and monitoring" would be approximately $125,000 *per qualified entity*. This is an unreasonably high amount – based on the wage, overhead, and fringe rates cited in the Regulatory Impact Analysis for the Proposed Rule (76 FR 33582), this would be equivalent to CMS dedicating 1.4 FTE of its professional staff to *each* qualified entity to do nothing more than process the qualified entity's application and monitor its activities. In total, this means that CMS would be dedicating the equivalent of 35-45 full-time professional staff to carry out these functions, which we believe is excessive and unnecessary.

We believe that fees as large as what CMS is proposing in the regulation would make it difficult or impossible for many smaller communities to obtain Medicare claims data and generate quality measures for their citizens, physicians, and hospitals. We do not believe that Congress envisioned CMS imposing large administrative fees on local communities to support CMS staff operations or creating financial barriers for small communities to access Medicare claims data for measurement and reporting purposes.

Indeed, charging high amounts to access the data could actually increase costs for the Medicare program. A major reason that communities are working to measure and report on the quality and cost of healthcare in their communities is to encourage

and assist physicians and hospitals to improve the efficiency and effectiveness of care delivery. Lack of access to Medicare data has been a major barrier to communities' ability to pursue higher-value healthcare, and if high fees continue to preclude that access, the Medicare program will lose the opportunity to gain cost savings in healthcare delivery.

**We urge that CMS limit the fees charged for access to Medicare claims data to the direct costs of generating those data. If fees to cover administrative costs of processing applications and monitoring qualified entities must be charged, those costs should be significantly reduced below the levels projected in the Proposed Rule and should be set with consideration for the potential savings to the Medicare program from the higher-quality, lower-cost healthcare delivery that the qualified entity's measurement and reporting efforts will help stimulate.**

## D. Content and Scope of Data

The Proposed Rule states that claims data "would be limited to the geographic spread of the qualified entity's other claims data as determined by CMS." This may be too restrictive in some cases, particularly depending on the nature of the measures that are being reported. Some measures, such as processes of care, will be focused on services delivered by the *providers or suppliers that are located within the region* served by the qualified entity, regardless of where the patients reside, but other measures, such as outcomes and costs, will focus on *all services received by Medicare beneficiaries who live within that geographic area*, and may include services from providers or suppliers from a much broader geographic area, including other states. Just because the patients represented in a non-Medicare set of claims data used by the qualified entity (e.g., Medicaid recipients) do not receive care in another state does not mean that CMS should exclude claims from that state in the Medicare claims data provided to the qualified entity.

We also want to ensure that, to the maximum extent possible, the "standardized extracts" of data enable all claims to be linked to the providers and suppliers who were involved with delivering the services or prescribing the pharmaceuticals represented in the claims, ideally including the physicians which were involved with hospital services. This is essential for being able to attribute costs and quality to the appropriate providers and suppliers.

**We recommend that §401.705(e)(1) be revised to read as follows:**

> **(1) CMS would release standardized extracts of encrypted data from Medicare parts A and B claims data, and <u>part</u> D [sic] drug event data for the most recent three years of data available at that time. <u>These extracts will include the identifiers for all providers and suppliers involved with the services associated with each claim</u>. The data would be limited to (1) <u>claims associated with the Medicare beneficiaries residing in the geographic area and (2) claims</u>**

**associated with the providers and suppliers located in the geographic ~~spread~~ area from which ~~of~~ the qualified entity's other claims data are drawn ~~as determined by CMS~~.**

## E. Frequency of Data

The Proposed Rule specifies that CMS would only provide qualified entities with claims data on a yearly basis. As a practical matter, this would mean that any measures reported by a qualified entity would reflect services that were delivered as much as two years in the past.

Although some qualified entities may wish to calculate and report measures only on an annual basis, others will likely want to update measures more frequently so that citizens have more current measures of quality and cost and to support efforts by physicians and hospitals to engage in rapid-cycle improvement.

The Affordable Care Act does not require that claims data only be released annually; indeed, Section 1874(e)(3) authorizes release of data for "specified geographic areas and time periods requested by a qualified entity." CMS can charge more to release data more frequently, thereby avoiding having qualified entities requesting data more frequently but not using it.

We recommend that CMS provide data as frequently as quarterly if requested by qualified entities. Depending on the number of claims involved and the nature of the measures, a qualified entity could either report measures on a quarterly basis (i.e., only based on activity during the most recent quarter), or on a rolling 12-month basis (i.e., using the most recent four quarters of data).

**We recommend that §401.705(e)(2) be revised to read as follows:**

**(2) After the ~~first year of participation~~initial set of data is provided, CMS would provide qualified entities with the most recent additional ~~year of~~ data ~~on a yearly basis~~at frequently as quarterly if requested by the qualified entity. Qualified entities would be required to pay a fee equal to the cost of CMS making ~~this~~ these data available before CMS would release the most recent ~~year of~~ additional data to the qualified entity.**

## F. Access to Beneficiary Names

We believe it is essential that qualified entities be able to receive a crosswalk which provides the patient names that are associated with the beneficiary identifiers in the encrypted data file at the same time that they receive the encrypted data file. In Section II.D of the Preamble to the Proposed Rule (76 FR 33574-33575), you acknowledge that providers and suppliers will need to have access to patient names in order to identify errors in measurement; in many cases, we believe that providers and

suppliers will also want to follow up with the specific patients that the measures indicate are not receiving high-quality or efficient care in order to make improvements.

Although you indicate that you considered an option for providing such a crosswalk file (the "first option" described on page 33574 of the Preamble to the Proposed Rule), you instead chose to propose a much more complex process (the "second option") that you acknowledge would be more resource intensive for both CMS and the qualified entity, namely, requiring that after a provider or supplier makes a specific request for names to the qualified entity, the qualified entity would then have to request those specific names from CMS, wait to receive those names, and only then be able to provide them to the provider or supplier.

You indicate that the basis for choosing this lengthy and costly process was to limit the release of patient names only to those cases where a provider or supplier requests them. In your Regulatory Impact Analysis on page 33582, you assume that only 25% of providers and suppliers would make such a request, but the actual number could be much higher, and even if only 25% of the providers and suppliers make the request, the proportion of patient names could be much higher if the largest providers routinely make the request. As a result, even under the approach that you have proposed, most or all patient names could still be released. But your proposed approach would also introduce considerable delays and complications into what could otherwise be a relatively straightforward process of computing measures, verifying them with providers and suppliers, and issuing the corrected measures to the public.

We strongly urge that you revise this and adopt the first option – providing the crosswalk file along with the claims data. The qualified entity would still only be permitted to release patient names to those providers which requested them, but it would be able to do so immediately and at far lower cost. Under this approach, the qualified entity would still have to have adequate mechanisms for protecting the beneficiary-identifiable data, the same as in the option you proposed.

**Consequently, we recommend that §401.705(e)(3) be added, which would read as follows:**

> **(3) In addition to the standardized extracts of encrypted data, CMS would provide the qualified entity with an additional file containing beneficiary identifiable data for all of the beneficiary identifiers in the encrypted data file, for the sole purpose of the qualified entity enabling providers and suppliers to verify the accuracy of measures and to determine which of their patients are not meeting quality or cost standards, if (A) the qualified entity requests this crosswalk and (B) the qualified entity demonstrates that it has adequate systems and procedures for protecting this information against unauthorized release.**

## G. Technical Assistance

In Section II.C. of the Preamble to the Proposed Rule (76 FR 33573), you requested comment on whether qualified entities would require any technical assistance to aid in understanding and working with Medicare data, what type of technical assistance would be beneficial, and whether you should include technical assistance in the fee charged for the data. It is difficult to anticipate exactly what kinds of technical assistance may be needed until the data are actually available, but it is likely that different qualified entities will need different types and levels of technical assistance depending on their experience in using Medicare data and the types of measures they are trying to generate.

**Since successful use of the Medicare claims data for quality and cost measurement will benefit the Medicare program, we urge CMS not to charge for reasonable levels of technical assistance in using the data, and to base any charges on the actual level of technical assistance provided, rather than charging all entities the same amount.**

You also indicated that you plan to encourage the development of a voluntary knowledge sharing mechanism for qualified entities to communicate with each other regarding best practices for calculating measures, designing reports, and other important elements of this program, and you requested comments on whether technical assistance is needed and how such a voluntary knowledge sharing mechanism would best be designed and operated. Regional Health Improvement Collaboratives already have mechanisms for sharing best practices and problem-solving through the Network for Regional Heatlhcare Improvement, and many Collaboratives also participate in other knowledge-sharing mechanisms such as the AHRQ CVE Learning Network. The most efficient method of providing technical assistance for the use of Medicare claims data would be to build on these existing mechanisms.

**Consequently, we urge CMS not to create new knowledge sharing mechanisms specific to the use of Medicare claims data, but to support the use of existing knowledge-sharing mechanisms such as through the Network for Regional Healthcare Improvement.**

# V. UPDATES TO PLANS (§401.706)

## A. Review and Approval of Changes

The Proposed Rule requires that before a qualified entity can make *any* changes to the measures it uses, to the reporting format it uses for already-approved measures, or even to the method by which it shares approved reports with the public, it must submit the changes to CMS 90 days prior to when it *wishes* to implement the changes. The qualified entity would be prohibited from making the changes without approval from CMS, and there is no deadline for CMS to respond.

We believe that the prohibition on using new measures without CMS approval should apply only to public release of measures, and that a qualified entity should be able to distribute new measures confidentially to providers without CMS approval, since this will be an important mechanism for testing whether the new measures will work properly.

We also believe that requiring CMS review and approval of all changes in reporting formats and public dissemination strategies is an unnecessarily burdensome level of micromanagement that will be expensive for both CMS and qualified entities and will severely impede the ability of qualified entities to implement successful measurement and reporting programs. The wording of the Proposed Rule implies that even the most trivial change in the format of a report or the method by which it is distributed must be submitted to CMS for review and cannot proceed without CMS's approval. Since there is no indication of how quickly CMS will respond when a change is submitted, a qualified entity could be left unable to issue quality reports at all if it concludes that its original reporting format was flawed or confusing but is unable to get approval from CMS to make the necessary changes.

The Proposed Rule is also written in a way which could unintentionally preclude a qualified entity from reporting on all of its measures if it has a problem with any one measure. For example, there may well be situations in which, after a qualified entity receives the data and computes a measure, it determines that that measure is inappropriate for publication or even for distribution to providers and suppliers on a confidential basis. The implication of the proposed wording is that if a provider wishes to drop a measure because of problems with implementing it, it would have to seek approval to proceed with reporting all of the other measures, even standard measures which have been reported in the past or are successfully being used in other communities. This would be inappropriate.

Finally, we believe it is inappropriate for CMS to impose these kinds of extensive requirements on applicants but provide no assurance of timely response. The need to expand the use and robustness of quality measurement efforts is urgent, and requires prompt action at both the community level and at CMS. We urge CMS to commit itself to a specific deadline for responding to changes submitted by qualified entities.

**We recommend that §401.706(a) and (b) be revised to read as follows:**

**(a) If a qualified entity wishes to make changes to:**

**(1) ~~Its list of~~ a proposed measure~~s~~, the qualified entity must send all the information referenced in § 401.704(a) for the ~~new~~ measure to CMS at least 90 days prior to its intended ~~confidential~~ release to the public. The new or revised measure may be released confidentially to providers of services and suppliers by the qualified entity while it is waiting for CMS review unless CMS specifically indicates that the qualified entity should not do so. If a**

**qualified entity wishes to drop a measure that it had previously proposed to report, it may do so without approval from CMS.**

**(2) Its proposed prototype report for a particular measure in a way that would significantly affect the way the performance of providers or suppliers is described, categorized, or ranked, the qualified entity must send the new prototype report to CMS at least 90 days prior to its intended confidential release to providers of services and suppliers.**

**(3) Its plans for sharing the reports with the public in a way that would significantly reduce the number of individuals who would see or be able to access the reports, the qualified entity must send the new plans to CMS at least 90 days prior to its intended ~~confidential release to providers of services and suppliers~~release to the public.**

**(b) CMS will notify the ~~The~~ qualified entity within 60 days if ~~would be notified when~~ its proposed changes are approved or denied for use. Under no circumstances may a qualified entity ~~issue a report, use a measure, or share a report~~ make the changes described in subsection (a) without first ~~obtaining~~ submitting them to CMS for approval. If CMS does not disapprove the changes within 60 days, the qualified entity may proceed to implement them.**

## B. Changes in the Amount of Data from Other Sources

§401.706(c) of the Proposed Rule requires that if the amount of claims data from other sources "decreases," the qualified entity must immediately inform CMS and describe whether the change in data would cause statistical reliability problems. Moreover, it states that "under no circumstances may a qualified entity issue a report, use a measure, or share a report" until CMS "determines that the remaining claims data is sufficient" or until the qualified entity acquires new data and submits new documentation acceptable to CMS.

This provision is unnecessarily restrictive and burdensome. The wording implies that the slightest reduction in claims data from other sources, even if there would be no impact on the statistical reliability of measures generated using the remaining data, would force a qualified entity to suspend its measurement and reporting activities until it submitted documentation to CMS proving that there would be no impact *and* CMS approved proceeding with the remaining data. Since there is no obligation on CMS to respond in a timely fashion, this requirement could create significant delays in a qualified entity's measurement and reporting efforts.

**We recommend that §401.706(c) be revised to read as follows:**

> **(c) If the amount of claims data from other sources available to a qualified entity significantly decreases, the qualified entity must immediately inform CMS.**
>
> **(1) If the qualified entity ~~and~~ submits documentation that the remaining claims data from other sources is sufficient to address the methodological concerns regarding sample size and reliability, it may continue to use Medicare data for its approved measures. ~~Under no circumstances may a qualified entity issue a report, use a measure, or share a report after this point.~~**
>
> **(~~1~~2) If the qualified entity cannot submit such documentation, or if CMS determines that the remaining claims data is not sufficient, the qualified entity would suspend the use of Medicare claims data until it either ~~have 60 days to~~ acquired new data or ~~and~~ submitted ~~new documentation~~ a revised plan for measurement to CMS that could successfully use the available data. If after ~~6~~180 days, the qualified entity does not have access to new data or if it cannot submit a revised measurement plan for using the existing data that is satisfactory to CMS ~~decides the qualified entity still does not possess the need amount of additional claims data~~, CMS shall terminate its relationship with the qualified entity.**
>
> **~~(2) If CMS determines that the remaining claims data is sufficient, the qualified entity may resume issuing reports, using measures, and sharing reports.~~**

# VI. ENSURING THE PRIVACY AND SECURITY OF DATA (§401.707)

We support the requirement that a qualified entity comply with the requirements of a data use agreement with CMS. Qualified entities will have similar agreements with other payers in order to obtain their claims data.

**We recommend that the current CMS Data Use Agreement (DUA) be modified to ensure that it easily enables the type of measurement and reporting initiatives authorized under the regulations.** For example, the prohibition on linking records in Section 10 of the DUA should be eliminated.

**We also recommend that the DUA explicitly authorize the use of the measures generated with the data for quality improvement programs, pay-for-performance initiatives, etc.**

# VII. SELECTION AND USE OF PERFORMANCE MEASURES (§401.708)

## A. Use of Standard Measures

We support the use of NQF-endorsed measures wherever possible. However, the Proposed Rule defines "standard measures" as those which "can be calculated" from claims data, and this may unintentionally preclude the use of "clinically enhanced" measures that combine claims data with laboratory results, electronic health record information, etc.

**We recommend that §401.708(a) be revised to read as follows:**

> **(a) *Standard measure.* A standard measure is defined as a measure that can be calculated <u>in whole or in part</u> from the standardized extracts of Medicare Parts A and B claims, and Part D drug event data that:**

## B. Use of Alternative Measures

Section 1874(e)(4)(B)(ii)(II) of the Social Security Act (added by Section 10332 of the Affordable Care Act) requires a qualified entity to use measures and measure specifications that have been endorsed by the National Quality Forum "if available," and Section 1874(e)(4)(B)(ii)(II) permits a qualified entity to use alternative measures "if the Secretary, in consultation with appropriate stakeholders, determines that use of such alternative measures would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by such standard measures." The law clearly states a preference for using standard, NQF-endorsed measures where they are available, but also provides flexibility for qualified entities to use additional or different measures when appropriate.

In Section II.B.2. of the Preamble to the Proposed Rule (76 FR 33570), CMS notes that there are several areas of performance measurement with very few standard measures, states that it hopes to "encourage innovation in the development of new claims-based measures to evaluate the performance of providers of services and suppliers," and indicates its belief that "allowing qualified entities to propose the use of alternative measures encourages the development of additional claims-based performance measures."

However, the Proposed Rule requires that alternative measures can only be used after they are published for notice and comment using the formal rulemaking process, an extremely expensive and time-consuming approach. The Proposed Rule would only allow alternative measures to be submitted to CMS once each year, by May 31; even if it were approved, the alternative measure could not be used until the following calendar year because of the six months it takes to go through the notice and comment process. Because of this lengthy and burdensome process, no qualified entity

could use an alternative measure in 2012, even if it were ultimately determined to be better than available standard measures. It is quite clear that this burdensome process will not encourage innovation, and will likely repress it. Consequently, we strongly urge that CMS establish a faster and less burdensome process for reviewing and approving the use of alternative measures.

The law does not require the use of a formal notice and comment process; it requires only that the Secretary "consult with appropriate stakeholders," and there are faster and more cost-effective ways of consulting with stakeholders than using a formal notice and comment procedure. For example, the National Quality Forum has established a Measure Applications Partnership with a broad, multi-stakeholder membership that could provide feedback to the Secretary on proposed measures. We believe that an even more appropriate process would be for a qualified entity that wishes to use an alternative measure to solicit input from the stakeholders in its community, since they would be the most directly affected by the measure and provide the most relevant information regarding whether an alternative measure would be "more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures." The qualified entity could provide a summary of this input to the Secretary to justify the use of the alternative measure in its community.

We believe that many qualified entities will need and want to use alternative measures for several reasons. For example, some Regional Health Improvement Collaboratives have been using composite measures of the quality of care for diabetes for several years, but NQF only endorsed these measures this spring. In some cases, a community may have begun reporting on a particular measure before a different NQF measure was endorsed, and the community now wants to continue using the same measure so that it can measure changes in performance over time. In some cases, a community may not feel that an NQF-endorsed measure addresses the most important aspects of care or the most important patient populations, or the community may determine that the current specifications for the numerator and/or denominator of the measure need to be modified to more accurately or fairly measure performance on that issue.

As with other aspects of the rule, we urge that CMS commit itself to a timely response to requests by qualified entities to use alternative measures.

**Consequently, we recommend that §401.708(b) be revised to read as follows:**

**(b) *Alternative measure.***

**(1) An alternative measure is defined as a measure that is not a standard measure, but that can be calculated in whole or in part from the standardized extracts of Medicare Parts A and B claims, and Part D drug event data that:**

**(i) Has been found by the Secretary ~~through a notice and comment rulemaking process,~~ to be more valid, reliable, responsive to consumer preferences, cost-effective, consistent with local quality improvement initiatives or past measurement efforts, or relevant to dimensions of quality and resource use not addressed by standard measures, and,**

**(ii) Is used by a qualified entity in a manner that follows the measure specifications as written ~~(or as adopted through notice and comment rulemaking)~~, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.**

**(2) If, subsequent to a qualified entity's use of an ~~An~~ alternative measure, ~~may be used up until the point that~~ a standard measure for the particular clinical area or condition becomes available, ~~at which point~~ the qualified entity must switch to the standard measure within ~~6 months or submit additional scientific justification and receive approval from~~ 2 years unless the Secretary ~~to~~ has approved continued use of ~~continue using~~ the alternative measure.**

**(3) To ~~submit~~ receive approval to use an alternative measure ~~for consideration for use in the following calendar year~~ an entity must submit the following ~~by May 31st~~information:**

**(i) The name of the alternative measure.**

**(ii) The name of the alternative measure's developer or owner.**

**(iii) Detailed specifications for the alternative measure.**

**(iv) Information demonstrating how the alternative measure is more cost-effective, relevant to consumer preferences, cost-effective, consistent with local quality improvement initiatives or past measurement efforts, or relevant to dimensions of quality and resource use not addressed by standard measures.**

**(v) Documentation that input on the alternative measure has been solicited from the providers or suppliers which would be measured, and the comments received from those suppliers and providers.**

**(4) CMS will either approve or disapprove the alternative measure within 60 days following receipt of the request from a qualified entity.**

# VIII. REQUESTS FOR ERROR CORRECTION (§401.709)

As explained in more detail under IV-F above, we believe that the process you have proposed for having qualified entities request beneficiary names from CMS in response to specific provider requests is cumbersome, expensive, and unnecessary. We urge that a qualified entity receive a crosswalk which indicates the patient names associated with the beneficiary identifiers in the encrypted data file at the same time that it receives the data file.

**In addition to adding §401.705(e)(3) as described earlier, we recommend that §401.709(c) be revised to read as follows:**

> **(d) If a qualified entity receives a request for beneficiary names from a provider of services or supplier, the qualified entity must provide access to the names in a manner which ensures the privacy and security of the data.~~forward that request to CMS including a copy of the signed request from the provider of services or supplier as an attachment~~.**
>
> **~~(1) After the qualified entity receives the beneficiary names from CMS and sends the information to the requesting provider of services or supplier, the qualified entity must immediately destroy that data and is not permitted to retain or use the beneficiary names in any way.~~**
>
> **~~(2) If a qualified entity does not immediately destroy all identifiable data after sharing the information with the requesting provider of services or supplier, it will be subject to the penalties referenced in § 401.710(d).~~**

# IX. MONITORING AND SANCTIONING OF QUALIFIED ENTITIES (§401.710)

Even though each of the monitoring and reporting requirements included in §401.710 of the Proposed Rule is individually reasonable, the full set of requirements could be quite burdensome for many organizations. This could have the unintended consequence of discouraging communities from applying and thereby reduce the number of communities using Medicare data to support quality measurement programs.

**We urge that CMS do everything possible to simplify the monitoring and reporting process in order to reduce costs for applicants and encourage broad use of Medicare claims data for quality measurement and reporting.**

We greatly appreciate the opportunity to provide these comments, and we would be happy to answer any questions or provide any additional information that you would find helpful.

Sincerely,

Harold D. Miller
President and CEO

cc: Colleen Bruce, CMS
Jonathan Blum, CMS
Patrick Conway, CMS
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NRHI Members