BACKGROUND PAPER FOR SEPTEMBER 20, 2010 LISTENING SESSION:

Section 10332 of The Patient Protection and Affordable Care Act:

Availability of Medicare Data for Performance Measurement

Summary of the Legislative Requirements

Section 10332 of the Patient Protection and Affordable Care Act (ACA) adds a new subsection to Section 1874 of the Social Security Act, requiring that the Secretary establish a process to allow for the use of standardized extracts of Medicare Parts A, B, and D claims data to evaluate and report on the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use. The effective date of this section is January 1, 2012.

The statute defines QEs as public or private entities that are determined by the Secretary as qualified to use Medicare claims data to make such evaluations of provider/supplier performance, and that agree to meet specific requirements regarding the transparency of their methods and the appropriate use and protection of Medicare data. The statute requires that Medicare claims extracts be combined with other claims data, although the statute is not specific on what, or how much, other claims data should be combined with Medicare claims data. The statute requires that the only use of such data and the derived performance information about providers and suppliers be in reports in an aggregate form, released and made available to the public, after first making such reports available to any identified provider or supplier for their opportunity to appeal and correct errors. The statute also instructs the Secretary to take such actions as she deems necessary to protect the identity of individual beneficiaries, and authorizes her to establish additional requirements that she may specify for QEs to meet, such as ensuring the security of data. The Medicare claims extracts are to be made available to QEs at a fee equal to the cost of making such data available, which will be deposited into the Part B Trust Fund.

On September 20, 2010 the Centers for Medicare and Medicaid Services (CMS) will hold a Listening Session to elicit public input on implementing these provisions. This paper is intended to describe some of the key issues about which we seek input.

Background

In an effort to stimulate greater provider, purchaser, and patient awareness of quality and efficiency at the local level, there has been considerable activity and innovation in calculating and reporting performance metrics for physicians, practice sites, hospitals, and other providers at the local and regional levels in recent years. Examples of these efforts include efforts by national and regional health plans, the Wisconsin Collaborative for Health Care Quality, Minnesota Community Measurement, Massachusetts Health Quality Partners and the Pacific Business Group on Health, and others. These efforts range in size, scope, sophistication, and levels of measurement, with current estimates that there are more than 100 regional or national efforts engaged in quality measurement and improvement efforts of some type.[1] Many of these entities

[1] For example, AHRQ has identified over 100 community quality measurement efforts. http://ahrq.hhs.gov/qual/value/localnetworks.htm

have expressed an interest in combining Medicare data with private payer data in their performance measurement efforts. The interest in using Medicare data is often articulated because the relative size of Medicare enrollment makes it one of the largest payers in any given market, but also since Medicare serves an older and sicker population, claims data from Medicare provides more opportunities to assess care provided to the chronically ill and other populations than is found in commercial data. The goal expressed by those seeking this data is that, when coupled with other data, Medicare data can provide measurement initiatives, such as the ones described above, with greatly increased sample sizes upon which to calculate more reliable performance results and align payer measurement efforts.

Even without the specific direction provided by the ACA, there is a long history of CMS sharing Medicare claims for research and analysis purposes and some precedent for the release of Medicare claims for performance measurement purposes.

In the area of sharing Medicare data to assess clinician performance, CMS has engaged in two recent efforts. In 2006, CMS funded a Quality Improvement Organization (QIO) special project known as the Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) pilot project. Under the BQI project, the QIO subcontracted with 6 regional entities, or pilot sites, to test methods to aggregate Medicare A, B, and D claims data with claims data from commercial health plans, and in some cases Medicaid data, in order to calculate and report quality measures for physician groups, and in some cases, individual physicians.[2]

Additionally in 2009, CMS calculated 12 performance measures based on Medicare Parts A, B, and D claims for 2006 and 2007 in support of the Chartered Value Exchange (CVE) initiative.[3] The Generating Medicare Physician Quality Performance Measurement Results (GEM) project results were reported at the medical group practice and zip code level on CMS' website with the intent that CVEs could then combine the results with commercial claims data to develop a more comprehensive picture of medical group practice performance that could be publically reported.

However, neither of these two initiatives granted regional efforts the full flexibility they desired to use Medicare claims data for performance measurement. The BQI project was a time-limited special study that restricted the use of the Medicare claims data to the calculation of a specific set of 12 measures selected by the pilot sites and approved by CMS. Once the project ended, the pilot sites were not able to continue to receive or use Medicare claims data. Measure calculation and claims analysis for the GEM project was performed by CMS. The GEM data were not released to CVEs at the claim level, but rather as aggregated measure results reported at the medical group or zip code level. Some CVEs expressed frustration at this level of reporting and reported difficulty in merging the GEM results with other data due to inconsistent Medicare and private sector unique identifiers for medical groups.

Key Issues

The law grants the Secretary latitude in designing the parameters, terms, and definitions of the

[2] The 6 communities were in Arizona, California, Minnesota, Wisconsin, Indiana, and Massachusetts. More information on the BQI project can be found here: http://www.cms.gov/BQI/
[3] http://www.cms.gov/GEM/

Medicare claims data release to QEs. The choices made regarding these parameters will have significant impact on issues such as: methods used to assure the security of beneficiary data; the number and type of measures reported by QEs; the amount and type of data released by CMS; the costs and burden to CMS of evaluating QE applications and producing data extracts; and the reactions of providers, suppliers, consumers, and other stakeholders to the implementation of this provision. We have identified key decision parameters to include:

- QE eligibility and operating criteria
- Measure selection and use by QEs
- Data extraction and distribution
- Data security and privacy
- Interaction with other CMS performance measurement and reporting efforts

We outline some of the key choices relative to these parameters below.

QE Eligibility and Operating Criteria

The law defines QEs as "a public or private entity that is qualified (as determined by the Secretary) to use claims data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness and resource use."

The law requires approved QEs to meet specific criteria along several key dimensions.[4]

- *Qualifications*
  - An entity wishing to become a QE must demonstrate to the Secretary for her determination that it is qualified to use claim data to evaluate the performance of providers on measures of quality, efficiency, effectiveness, and resource use.

- *Transparency and Validity of Measures, Methods and Reports*
  - QEs shall submit a description of the methodologies that they will use to evaluate the performance of providers of services and suppliers using such data to the Secretary;
  - QEs shall include in their reports an understandable description of the methods involved in creating the reports including risk adjustment and attribution methods, data specifications and limitations, and the sponsors of such reports so that consumers, providers, health plans, researchers, and other stakeholders can assess the validity of such reports;
  - QEs shall use measures endorsed by the entity with a contract under Section 1890(a) of the Social Security Act and measures developed pursuant to Section 931 of the Public Health Service Act if available, or alternative measures if the Secretary, in consultation with appropriate stakeholders, determines that such

[4] Many of these criteria conform loosely to the requirements laid out in the "Patient Charter for Physician Performance, Measurement and Tiering Programs," a set of standards agreed to by both leading physician groups and health insurers, as well as consumer, labor and employer organizations, about how physician performance should be measured and reported to consumers. For more information please refer to the following link: http://healthcaredisclosure.org/docs/files/PatientCharter.pdf

measures 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;
    - QEs shall submit the format of any reports produced to the Secretary prior to publication; and
    - QEs shall release and make all reports available to the public (after providers have had the chance to review and appeal them confidentially).

- *Provider Rights*
    - QEs shall make available to any providers of services or suppliers subject to evaluation, upon their request, data available under this subsection;
    - QEs shall, prior to the public release of any reports, make them available confidentially to any providers identified in order to provide them with an opportunity to appeal or correct errors in the report; and
    - The data released to a QE under this subsection shall not be subject to discovery or admission as evidence in judicial or administrative proceedings without the provider's consent.

- *Data Privacy and Security*
    - QEs shall only include information on a provider in an aggregated form as determined appropriate by the Secretary;
    - The Secretary must take necessary actions to protect the identity of individual beneficiaries;
    - QEs must agree to meet the Secretary's requirements regarding ensuring the security of the data; and
    - QEs shall only use Medicare claims data released under this section for the intended purpose (i.e., the production and public release of aggregate level provider performance reports).

In addition to ensuring that QEs meet these specific operating criteria, CMS will have to define basic eligibility requirements for QEs. The stringency (or lack thereof) of the basic requirements established by CMS regarding eligibility will play a large role in determining both the number and types of organizations approved to be QEs. If eligibility requirements are too lenient for the organizations that may be QEs, it could have downstream implications for data security, beneficiary privacy, and the quality of measure calculation and performance reports. However, eligibility requirements that are too strict may result in limited use of Medicare performance information to inform consumer choice or provider improvement efforts.

QEs will have to demonstrate to CMS significant and sophisticated knowledge regarding their ability to combine large data sets, calculate measures, protect the integrity and security of Medicare data, report measures, and engage providers. Prior experience with the BQI project and other measurement efforts that have sought to combine data from multiple payers has shown that it is a time and resource-intensive undertaking. In addition, the science of developing provider performance reports that provide actionable information to providers is still in its relative infancy and QEs may have to invest significant resources in testing effective report templates. Finally, QEs will also have to commit resources to ensuring they can adhere to rigorous data security

requirements.

An additional important component of the statute is the requirement for QEs to combine any Medicare data extracts with claims data from other sources. The Secretary may have to define what other forms of claims data are appropriate, and how much of this data QEs should demonstrate they possess or are able to obtain in order to receive Medicare claims data extracts.

Measure Selection and Use by QEs

The statute provides for different classifications of measures that could potentially be used by QEs in calculating performance results for providers and suppliers.

- Standard measures, such as those endorsed by the entity with a contract under Section 1890(a) of the Social Security Act and those developed under Section 931 of the Public Health Service Act
- Alternative measures, if they are determined by the Secretary, in consultation with stakeholders, to be more valid, reliable, responsive, or cost-effective than the standard measures or relevant to dimensions of quality and resource use not addressed by the standard measures.

Regardless of which measures are ultimately approved under Section 10332, all measures must be calculated using claims data. The statute describes the data as standardized extracts based on Parts A, B, and D claims data for items and services.

Standard measures

The National Quality Forum (NQF), which is the entity with a current contract under Section 1890(a) of the Social Security Act, endorses national standards for measuring and publicly reporting on performance through a consensus process. It works to ensure that any nationally-endorsed provider performance measure is subject to multi-stakeholder input to ensure each is scientifically valid, addresses clear performance needs, and can be calculated in a manner that does not impose undue burden on providers. There are currently hundreds of NQF-endorsed quality measures covering a range of clinicians, settings and specialties, although not all of these measures can be calculated using claims data. Additionally, although the statute explicitly references efficiency, effectiveness, and resource use measures, to date there are few NQF-endorsed measures in these areas.

The ACA added Section 931 to the Public Health Service Act and authorizes $75 million in fiscal years 2010 through 2014 to award grants, contracts, or intergovernmental agreements to eligible entities for the purposes of developing, improving, updating, or expanding quality measures for use in Federal health programs. While no funding has been appropriated under Section 931and no measures have been developed, any measures developed pursuant to this section would be eligible for use by QEs.

Alternative Measures

The statute also provides for the option to use "alternative" measures, but only following a special determination by the Secretary, in consultation with stakeholders that such alternative measures are more valid, reliable, responsive, or cost-effective than the standard measures or relevant to dimensions of quality and resource use not addressed by the standard measures. This clause provides substantial potential discretion to the Secretary for identifying what constitutes an appropriate set of measures. Depending on how this discretion is used, however, there is the potential for significant concern from either stakeholders seeking broader release and use of Medicare data or those seeking more limited release and use. For example, given the widespread attention to affordability of care, it is reasonable to assume that many QEs may be interested in obtaining Medicare claims data in order to calculate cost of care measures. However, currently few of these types of measures are endorsed by NQF.

Data Extraction and Distribution Process

The statute instructs the Secretary to provide QEs with standardized extracts of Medicare Parts A, B, and D claims data for one or more specific geographic areas and time. The statute does not define what specific data elements a standardized extract of claims data should contain. A "standardized extract" could be defined as a subset of elements normally contained on Medicare claims data files that would be anticipated for performance measurement, e.g., procedure code and diagnosis code(s), date and place of service, billed, and allowed charge. We seek comments from prospective QEs and other stakeholders on the definition of standardized extracts.

CMS will need to determine the scope of data extracts with regard to geography, time period, and, potentially, other factors. The ACA requires that QEs be provided with data for "one or more specified geographic areas". How these areas would be defined raises several issues, including how large or small an area would be and whether an area would be defined by where the beneficiary lives or where the provider practices. QEs are likely to request extracts of data for additional geographic areas besides their own to enable them to compare regional and local provider performance. QEs may request multiple years of data, although Part D data is only available from 2006 onwards, to provide for both trending information and, potentially, the pooling of data across multiple years to achieve more statistically sound results.

Data Privacy and Security

CMS has devoted considerable effort over a period of years to exploring how to use our claims data to support performance reporting and improvement initiatives while balancing the privacy requirements of beneficiaries and the concerns of individual physicians about the accuracy of such reports. Section 10332 clarifies the circumstances under which Medicare claims can be released for such measurement. The statute underscores the need for substantial processes to protect the interests of providers; Section 10332 also affirms ongoing obligation on the Secretary to protect Medicare beneficiary identity, and the release of data must not jeopardize this.

Interaction with other CMS Measurement and Reporting Efforts

An important consideration in the implementation of Section 10332 is how it might interact with the numerous quality and cost measurement efforts that CMS currently operates, and other measurement or reporting efforts that seek to fulfill ACA requirements. There are a number of existing programs that currently report performance information to providers, including a variety of "Compare" websites, the Physician Quality Reporting Initiative (PQRI), including the PQRI Group Practice Reporting Option (GPRO), and the Hospital Inpatient Quality Reporting Program.

Some of the legislative provisions in the ACA that require the calculation and reporting of performance measures to providers include:

- Section 3003: Expands the existing physician resource use measurement and reporting program and calls for the development of a public domain episode grouper which, starting in 2012, would be used to provide confidential reports to physicians comparatively measuring their resources for an assigned number of beneficiaries.
- Sections 3007: Establishes a value-based payment modifier starting in 2015 under which physicians Medicare fee-for-service (FFS) fee schedule payments will be adjusted by their combined performance on selected quality and resource use measures.
- Section 3022: Establishes a Medicare shared savings program, effective January 1, 2012. In order to qualify for shared savings payments, Accountable Care Organizations (ACOs) must meet certain quality performance thresholds, as defined by the Secretary, and reduce overall costs for their assigned population.
- Section 10331: Requires CMS to establish a Physician Compare website with information on physicians enrolled in the Medicare program and other eligible professionals who participate in PQRI, including information on physician performance.

When one views Section 10332 in the context of other ACA provisions, as well as the range of other performance measurement activities currently ongoing in both the public and private sectors, a number of issues emerge about how to ensure that the activities established under Section 10332 will supplement and support other quality reporting and performance improvement initiatives and not create confusing or contradictory information. Examples of questions that CMS believes are worth considering as it implements Section 10332 are:

- What are the implications of multiple measurement efforts – both within CMS, across the federal government and across the public and private sectors -- targeting the same providers? Are there specific steps that can be taken to address these issues?
- How will the claims-based measures calculated under Section 10332 interact with the meaningful use provisions in the Health Information Technology for Economic and Clinical Health (HITECH) Act?

Stakeholder Questions for Listening Session
The questions below are intended to elicit public input on the issues discussed previously in this paper.

- What types of eligibility criteria should QEs be subject to?
- What types of information should the Secretary collect on the QE application?
- What process will HHS use for ongoing monitoring of QEs to ensure compliance with requirements in the statute?
- What types of criteria or processes should be put in place to ensure beneficiary privacy and security of data?
- How, if at all, should the Secretary define a provider or services or a supplier?
- What types of measures are appropriate for use by QEs in generating performance reports?
- What should the process be for approving and using alternative measures to those that are endorsed by the entity under Section 1890(a) of the Social Security Act or under Section 931 of the Public Health Service Act?
- For endorsed measures, how much flexibility, if any, should QEs be given to modify measure specifications in the implementation of the measures?
- What types of claims data extracts are necessary for QEs to produce performance reports?
- How much data in addition to a QE's local area will likely be requested?
- What type of beneficiary and provider identifiers would potential QEs need to calculate measure results?
- What other claims data sources are appropriate for use with Medicare claims extracts in producing performance reports?
- How much additional claims data should be required of QEs for use with Medicare claims extracts in producing performance reports?
- What documentation should be required for data requests?
- What is the anticipated frequency of data requests by QEs?
- What is the expiration of the use of the data?
- Should there be any federal standards regarding the appearance, format, content and/or structure of reports generated by QEs?
- What type of appeals processes should QEs provide?
- How frequently will QE reports be generated and how long will reports be valid?
- How will reports be used to communicate to providers in a way that brings about improvements in health care?
- How will QEs protect beneficiary identities in the reports and in the appeals process?
- What concerns do health care providers and suppliers have about the Medicare data availability program? What requirements should the Secretary establish to help address those concerns?
- What concerns do consumers or other stakeholders that seek to use the results of performance information have about the Medicare data availability program? What requirements or features should the Secretary establish to address those concerns?