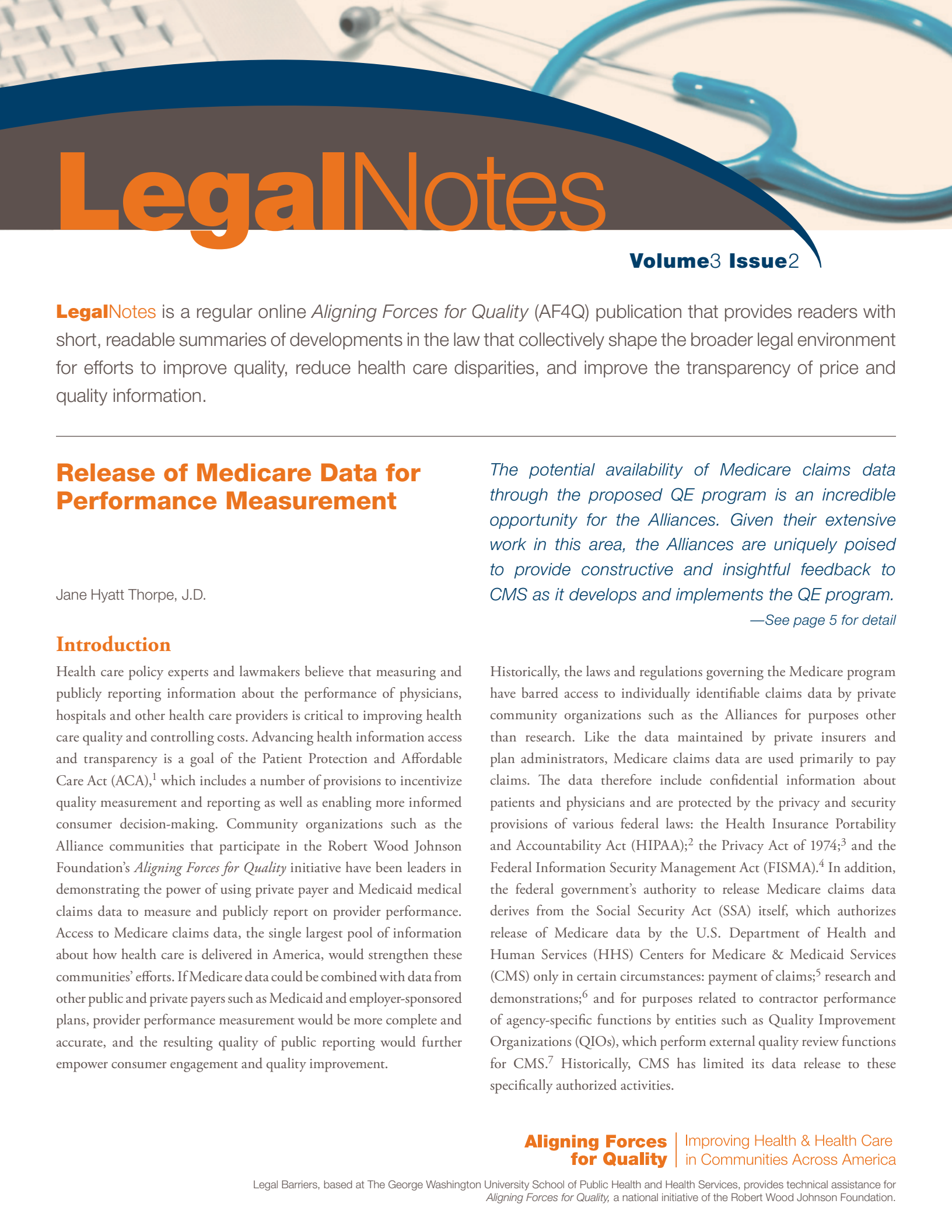




LegalNotes

Volume3 Issue2

LegalNotes is a regular online *Aligning Forces for Quality* (AF4Q) publication that provides readers with short, readable summaries of developments in the law that collectively shape the broader legal environment for efforts to improve quality, reduce health care disparities, and improve the transparency of price and quality information.

Release of Medicare Data for Performance Measurement

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Introduction

Health care policy experts and lawmakers believe that measuring and publicly reporting information about the performance of physicians, hospitals and other health care providers is critical to improving health care quality and controlling costs. Advancing health information access and transparency is a goal of the Patient Protection and Affordable Care Act (ACA),¹ which includes a number of provisions to incentivize quality measurement and reporting as well as enabling more informed consumer decision-making. Community organizations such as the Alliance communities that participate in the Robert Wood Johnson Foundation's *Aligning Forces for Quality* initiative have been leaders in demonstrating the power of using private payer and Medicaid medical claims data to measure and publicly report on provider performance. Access to Medicare claims data, the single largest pool of information about how health care is delivered in America, would strengthen these communities' efforts. If Medicare data could be combined with data from other public and private payers such as Medicaid and employer-sponsored plans, provider performance measurement would be more complete and accurate, and the resulting quality of public reporting would further empower consumer engagement and quality improvement.

The potential availability of Medicare claims data through the proposed QE program is an incredible opportunity for the Alliances. Given their extensive work in this area, the Alliances are uniquely poised to provide constructive and insightful feedback to CMS as it develops and implements the QE program.

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Historically, the laws and regulations governing the Medicare program have barred access to individually identifiable claims data by private community organizations such as the Alliances for purposes other than research. Like the data maintained by private insurers and plan administrators, Medicare claims data are used primarily to pay claims. The data therefore include confidential information about patients and physicians and are protected by the privacy and security provisions of various federal laws: the Health Insurance Portability and Accountability Act (HIPAA);² the Privacy Act of 1974;³ and the Federal Information Security Management Act (FISMA).⁴ In addition, the federal government's authority to release Medicare claims data derives from the Social Security Act (SSA) itself, which authorizes release of Medicare data by the U.S. Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) only in certain circumstances: payment of claims;⁵ research and demonstrations;⁶ and for purposes related to contractor performance of agency-specific functions by entities such as Quality Improvement Organizations (QIOs), which perform external quality review functions for CMS.⁷ Historically, CMS has limited its data release to these specifically authorized activities.

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Legal Barriers, based at The George Washington University School of Public Health and Health Services, provides technical assistance for *Aligning Forces for Quality*, a national initiative of the Robert Wood Johnson Foundation.

Over the past several years, as data access for performance measurement, public reporting and consumer engagement has grown as a public policy issue, CMS has developed additional approaches to releasing data for quality improvement purposes. For example, the agency has released Medicare claims data to QIO subcontractors to generate consensus-based physician quality measurements.⁸ Similarly, CMS has used Medicare claims data to generate and publish performance information at the physician practice level.⁹ Finally, in accordance with Congressional expectations and authorization regarding greater health information transparency and support for patients and consumers, CMS now releases significant amounts of institutional quality performance information on its *Compare* websites (e.g., Hospital Compare).¹⁰ Through these expanded activities, CMS has sought to use data in more innovative ways and to generate cross-payer comparisons of health care services and payment. However, these initiatives still fall short of a general policy allowing access to Medicare data by private and public third-party entities engaged in community-based cross-payer performance measurement.

The ACA Significantly Expands HHS Authority to Release Medicare Claims Data

The ACA significantly expands CMS' authority to release Medicare claims data.¹¹ However, the actual release of Medicare claims data is limited by very specific statutory parameters that are mirrored in the proposed implementing regulations. Specifically, the ACA directs the HHS Secretary (acting through CMS) to release Medicare claims data to "Qualified Entities" (QEs) for the sole purpose of evaluating and publicly reporting the performance of providers and suppliers.¹² A "qualified entity" is defined as a public or private entity that "is qualified...to use claims data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use" and that agrees to meet applicable legal requirements, including ensuring data security.¹³ Medicare claims data covered under the ACA encompass "standardized extracts" of Parts A and B (including inpatient hospital, outpatient hospital, skilled nursing facility, home health, hospice services, physician/supplier and DME claims) and Part D (prescription drug) data, in circumstances in which the entity can meet beneficiary privacy protection requirements.¹⁴ The ACA further specifies the types of measures QEs may use to measure performance and authorizes the Secretary to charge QEs a fee equal to the cost of making the data available.¹⁵ The ACA effective date is January 1, 2012.

On June 8, 2011, CMS issued a notice of proposed rulemaking (NPRM) implementing the ACA Medicare data release provisions; comments are due by August 8.¹⁶ Key highlights of the NPRM are as follows:

Selection of QEs

- CMS proposes to set standards for certifying QEs and will release Medicare claims data to all QEs that meet the required standards. The agency does not propose to create exclusive franchises, but rather permit competing QEs in the same geographic area. CMS recognizes that this may result in providers and suppliers getting performance reports from multiple QEs and is seeking comment on whether it should cap the number of QEs in a given area or introduce other mechanisms for addressing the multiple report issue. CMS does not address the issue of whether a QE could be national in scope, although it does not propose to release national feeds of Medicare claims data, only data for specific geographic regions.
- QEs will be evaluated based on (1) organizational and governance capabilities, (2) access to and addition of claims data from other sources (e.g., private payer, Medicaid), and (3) data privacy and security capabilities.
- CMS emphasizes that it is looking for QE applicants with experience using claims data to measure performance. Although the NPRM indicates that the agency will consider applicants with less experience, CMS proposes at least three years of experience including an established track record of profiling providers and suppliers.
- CMS is proposing to require the following information in the QE application:
 1. Name and description.
 2. Description of organizational and governance qualifications.
 3. Description of business model, including coverage for cost of required functions (e.g., public reports) and cost of the data.
 4. Description of the additional claims data (e.g., private payer, Medicaid) and amount of data the applicant plans to combine with requested Medicare data. CMS proposes to consider only those applicants that have data from other sources at the time of their application.
 5. Description of geographic area(s) for which Medicare data is requested [CMS is proposing that this should match the geographic area(s) from which the applicant has other sources of data (e.g., state of Maryland)].

6. Documentation of data privacy and security policies and enforcement mechanisms.
 7. Descriptive information: name of the measure and measure developer; measure specifications; rationale for selecting those measures including the relationship of the measures to existing measurement efforts and relevance to the proposed population in the proposed geographic area; description of the methodologies proposed for use in creating reports; if seeking approval of an alternative measure, documentation that the proposed alternative measure has been accepted by the Secretary as an alternative measure through notice and comment rulemaking. It is important to note that these specifications come directly from the ACA, which requires QEs to submit a “description of the methodologies” and limits the measures that may be used by QEs to “standard measures” endorsed by the well-established process of the National Quality Forum (NQF), otherwise in use by other CMS programs, or developed under the authority of the Public Health Services Act.¹⁷ CMS proposes to post an official list of qualifying “standard measures” through subregulatory guidance.
 8. Description of the process the applicant will establish to allow providers and suppliers to review draft reports confidentially, request data and appeal to correct errors before the reports are made public.
 9. A prototype report for reporting findings to providers and suppliers, and if different, to consumers, including any standard explanatory language, an easily comprehensible description of the proposed measures, the rationale for use of those measures, a description of the methodologies to be used, and a description of the data specifications and limitations, as well as a dissemination plan for reports.
- CMS proposes an annual (rather than rolling) application process, with applications posted on the CMS website on January 1, 2012. Applications would be due March 31, 2012 and by close of first quarter each year thereafter.
 - CMS proposes to approve applicants for three-year periods from the date of CMS approval notification. Re-applications for subsequent three-year periods would be submitted six months before the end of the three-year period (updates/changes to original application).

Data and Measurement Requirements

- The NPRM provides that QEs will have to pay for data (cost to CMS of preparing plus technical assistance). CMS estimates that the approximate cost to provide a QE with three years of data covering 5 million beneficiaries would be \$275,000 (\$150,000 for the data and \$125,000 for the program costs).¹⁸ CMS seeks comments on the cost burden.
- CMS proposes to define claims data (whether Medicare or from other sources) “to be administrative claims data only, meaning, itemized billing statements from providers of services and suppliers that, except in the context of Part D drug event data, request reimbursement for a list of services and supplies that were provided to a Medicare beneficiary in the fee-for-service context or to a participant in another insurance or entitlement program. Data from other sources, such as registry data, chart abstracted data, or data from electronic medical records would not be considered claims data.”¹⁹
- CMS notes in the NPRM that it considered requiring QEs to have a threshold amount of additional (non-Medicare claims data), but decided against it. Instead the agency notes that it is considering requiring QEs to demonstrate their cross-payer analytic capabilities by holding claims data from two or more other sources; the agency seeks comments on a proposal that would require multiple data sources before a QE can participate.
- The NPRM would permit QEs to use only standard or approved alternative measures for provider and supplier performance evaluation as specified by the ACA.²⁰ A “standard measure” is one that has been endorsed by NQF, developed under new §931 of the Public Health Service Act, or adopted through notice-and-comment rulemaking and currently in use by CMS even if not endorsed by NQF. QEs may request approval from CMS to use alternative measures and there is a specific process identified for such requests, including an annual future notice-and-comment rulemaking process. CMS defines “alternative measure” as “a measure that is not a standard measure, but that can be calculated using only standardized extracts of Medicare parts A, B, and D claims, and that has been found by the Secretary to be more valid, reliable, responsive to consumer preferences, cost effective, or relevant to dimensions of quality and resource use not addressed by standard measures.”²¹
- CMS proposes to require QEs to produce provider AND supplier performance reports at least annually. CMS also proposes to bar QEs from using a report that has not been approved by CMS, even if CMS’s review takes longer than 90 days.

- The NPRM states that standardized data extracts will include information on final, adjudicated claims (as opposed to those that are only pending) from all seven claim types that are submitted for payment in the Medicare Fee-For-Service (FFS) Program (inpatient hospital, outpatient hospital, skilled nursing facility, home health, hospice services, physician/supplier and DME). It is important to note that Federally Qualified Health Center (FQHC) and Rural Health Clinic (RHC) data will not be included in the extracts as they do not bill Medicare on an FFS basis. This is an unfortunate omission particularly for underserved communities that are no exception to the lack of availability of comprehensive provider performance information. Extracts also will include Part D “drug event” information. CMS seeks comment on the extent to which QEs will need technical support to work with the Medicare claims data. The initial data feed will be three years, with additional years provided annually thereafter.
- Rather than providing a nationwide extract, CMS is proposing to limit the data to the geographic spread of the QE’s other claims data (e.g., state of Maryland) as noted above. CMS is seeking comments on whether QEs should have access to a nationwide extract of other data that would merit release of a nationwide extract of Medicare claims data.
- CMS proposes to require QEs to maintain a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III—Security of Federal Automated Information Systems,²⁴ as well as Federal Information Processing Standard 200 entitled “Minimum Security Requirements for Federal Information Systems,”²⁵ and Special Publication 800-53, “Recommended Security Controls for Federal Information Systems.”²⁶ CMS is also considering requiring some form of independent accreditation or certification of compliance with data privacy and security requirements from QEs.²⁷
- CMS proposes prohibiting the use of unsecured telecommunications to transmit beneficiary identifiable data or deductible information derived from any CMS data file(s). CMS also proposes to require QEs to disclose as part of their data privacy and security policies the circumstances under which data provided by CMS would be stored and/or transmitted.²⁸
- The NPRM would bar beneficiary-identifiable information from inclusion in public reports.

Privacy and Security

- CMS proposes not to provide individual beneficiary names in the standardized extracts of Medicare claims data. Rather, CMS proposes to include an encrypted beneficiary identifier that would permit linking of claims for the same beneficiary across multiple files and multiple years without identifying individual beneficiaries. However, CMS does recognize that “in order to enable adequate review opportunities for providers of services and suppliers and to promote increased provider acceptance of, and trust in claims-based quality measures,” release of beneficiary names to QEs—and by extension, to providers and suppliers—may be necessary.²² CMS proposes to provide beneficiary names to QEs only on a case-by-case basis for the purposes of responding to specific requests for data by providers and suppliers to verify performance measurement results prior to public reporting.
- CMS proposes to require QEs to execute a data use agreement (DUA) with CMS (the type of agreement that is required for CMS-approved research) that will stipulate privacy and security protections for the data.²³ The DUA will contain significant penalties for inappropriate disclosures of the data, including both civil monetary penalties and criminal penalties.
- CMS proposes to monitor the number of provider appeals to ensure the overall quality of individual QE reporting mechanisms and to identify any situations where providers of services or suppliers might be appealing on spurious grounds.
- CMS proposes to periodically audit QEs’ use of Medicare data for the production of performance reports on providers of services or suppliers to ensure that the Medicare data is being used only for its intended purpose, e.g., in combination with claims data from other sources to calculate and report either standard or alternative claims-based measures to providers of services and suppliers.
- CMS proposes to require QEs to submit an annual report to CMS addressing (1) general program adherence and (2) engagement of providers of services and suppliers.²⁹

Implications for Aligning Forces for Quality

The potential availability of Medicare claims data through the proposed QE program is an incredible opportunity for the Alliances. Provided they are able to meet the selection requirements, the Alliances will have access to three years, and then ongoing annual feeds, of Medicare claims data to augment the current private payer and Medicaid data they are currently using. The selection requirements will be rigorous, given the sensitivity of the data and related privacy and security requirements for its protection, and access costly. However, CMS indicated in the NPRM that it expects most applications will come from nonprofit organizations “such as existing community collaboratives.”³⁰

Given their extensive work in this area, the Alliances are uniquely poised to provide constructive and insightful feedback to CMS as it develops and implements the QE program. In particular, the Alliances should consider providing CMS with guidance on the following significant issues addressed in the NPRM:

- Ability of Alliances to meet privacy and security requirements.
- Ability of Alliances to cover the fees for the standardized extracts and whether this should be considered in the application process.
- Whether three years is an appropriate marker for experience working with claims data to measure and report provider performance.
- Whether CMS should consider applicants that are working to access non-Medicare claims data in addition to those that have non-Medicare claims data already in their possession.
- Whether there should be a specific threshold for the required non-Medicare claims data.
- Whether CMS should consider providing a national extract of Medicare claims data in addition to geographically based extracts. For example, would Alliances be interested in collaborating and merging data across regions to produce a national view of provider performance information?
- Insights concerning appropriate provider notice and review processes prior to public reporting.
- Insights concerning developing and publishing provider performance reports that are relevant to and accessible for consumers.
- Whether CMS should consider alternate methods to make available individually identifiable claims data to enable providers and suppliers to more fully review and act upon their performance measurement results.

Finally, of critical importance to ongoing performance measurement efforts is the issue of measuring resource use and cost that can be combined with quality measures to give a full view of the value of the care being delivered. The Alliances should highlight for CMS the importance of releasing relevant data and approving the use of “alternate measures” to measure provider resource use and cost in order to support the development of a standardized set of approved cost measures that mirror the standardized set of quality measures already in use.

Where possible, the Alliances should provide real-life examples of how the Alliances have addressed these or similar issues in their work using private payer and Medicaid claims data.

Beyond the work of the individual Alliances, the availability of all-payer provider performance measurement results generated by future QEs holds the potential to greatly improve the quality of care delivered, as well as the ability of consumers to be more informed and engaged in their health care decisions across the country. As a whole, the Alliances have the potential to continue to be leaders in the field—a trusted source for comprehensive, credible and actionable provider performance measurement information.

¹Patient Protection and Affordable Care Act of 2010 (PPACA), (Pub. L. No. 111-148).

²Health Insurance Portability and Accountability Act of 1996, (Pub. L. No. 104-191), 110 Stat. 139 (1996) (codified as amended in scattered sections of 42 U.S.C.).

³Privacy Act of 1974, (Pub. L. No. 93-579), 88 Stat. 1896 (codified as amended at 5 U.S.C. § 552a (2006)).

⁴Federal Information Security Management Act of 2002, 44 U.S.C. § 3544 (2006).

⁵Various authorities, including Social Security Act (SSA) § 1815, 42 U.S.C. § 1395g (2009) (hospitals); SSA § 1835, 42 U.S.C. § 1395n (2009) (physicians and other Part B providers); SSA § 1853, 42 U.S.C. 1395w-23 (2009) (MA plans); SSA § 1860D-12, 42 U.S.C. 1395w-112 (2009) (Part D plans).

⁶SSA § 1110, 42 U.S.C. §1310.

⁷SSA § 1154, 42 U.S.C. § 1320c-3.

⁸See the Better Quality Information for Medicare Beneficiaries (BQI) Project, <http://www.cms.hhs.gov/bqil/> (accessed June 1).

⁹See the Generating Medicare Physician Quality Performance Measurement Results (GEM) Project, <http://www.cms.hhs.gov/GEM/> (accessed June 1).

¹⁰See <http://www.hospitalcompare.hhs.gov/>; see also <http://www.medicare.gov/> to access other compare websites.

¹¹PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act §1874(e).

¹²PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act §1874(e)(1).

¹³PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act §1874(e)(2).

¹⁴PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act §1874(e)(3).

¹⁵PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act § (e)(4)(A) and (B).

¹⁶Medicare Program; Availability of Medicare Data for Performance Measurement, 76 Fed. Reg. 33566 (June 8, 2011).

¹⁷PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act §1874(e)(4)(B).

¹⁸76 Fed. Reg. at 33574.

¹⁹76 Fed. Reg. at 33568; proposed 42 C.F.R. § 401.702(d).

²⁰76 Fed. Reg. at 33569-71; proposed 42 C.F.R. § 401.708(a, b) and PPACA (Pub. L. 111-148) §10332 (2010), adding Social Security Act §1874(e)(4)(B).

²¹76 Fed. Reg. at 33570; proposed 42 C.F.R. § 401.708(a, b).

²²76 Fed. Reg. at 33575; proposed 42 C.F.R. § 401.709(d).

²³76 Fed. Reg. at 33576; proposed 42 C.F.R. § 401.707(a).

²⁴See <http://www.whitehouse.gov/omb/circulars/a130/a130.html>

²⁵See <http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>

²⁶See <http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf>

²⁷76 Fed. Reg. at 33576.

²⁸76 Fed. Reg. at 33576; proposed 42 C.F.R. § 401.707(a).

²⁹76 Fed. Reg. at 33579, proposed 42 C.F.R. § 401.710(b).

³⁰76 Fed. Reg. at 33582.