

Consumer-Purchaser DISCLOSURE PROJECT

Better information. Better decisions. Better health.

August 8, 2011

Donald Berwick, MD, MPP
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services

RE: Availability of Medicare Data for Performance Measurement

Dear Dr. Berwick:

The 38 undersigned organizations are from a collaboration of leading consumer, labor, and employer organizations committed to improving quality and affordability of health care through the use of performance information to inform consumer choice, payment, and quality improvement. We appreciate the opportunity to comment on the Availability of Medicare Data for Performance Measurement proposed rule.

We strongly support making Medicare data available so that reports on provider performance can be compiled. Greater transparency of provider performance is necessary to improve the quality, safety, and cost of health care and give consumers much needed information to make decisions. In addition, reports on provider performance give health plans and others information to guide contracting, tiering, benefit design, and pay-for-performance programs. Other industries provide comparative information on performance to enable consumer decision-making and stimulate market improvements. Health care should be no different. In fact, in health care, there is an even greater imperative to make useful information available because patients' lives and well-being are at stake.

Section 10332 of the Patient Protection and Affordable Care Act (ACA) requires CMS to share Medicare data with Qualified Entities for performance measurement and reporting on providers of services and suppliers, as long as protections of patient privacy and data security are in place, and the methods with which the data are used are transparent and subject to review by the public and affected providers and suppliers. In our view, however, many parts of the proposed rule will needlessly narrow access and use of Medicare data and could stifle innovation. We fear that under the proposed rule, the promise of having Medicare data available to improve quality and inform patient and clinical decisions will not be fully realized.

Below, we provide comments on areas of the proposed rule that are particularly important to consumers and purchasers. As an Appendix to this letter, we provide redlined changes to the proposed rule. We believe these changes and clarifications to the proposed rule will benefit both patients and providers.

www.healthcaredisclosure.org

Pacific Business Group on Health
221 Main Street, Suite 1500, San Francisco, CA 94105
415.281.8660 | tel

National Partnership for Women & Families
1875 Connecticut Avenue, NW Suite 650, Washington, DC 20009
202.986.2600 | tel

Permit the broadest possible use of Medicare data to achieve the greatest public benefit, while protecting patient privacy and data security. Data should be released to the maximum extent possible under the law, consistent with adequate protections for patient privacy and data security and with transparency of measurement methods. Quite properly, the law does not call on the Secretary to judge the merits of each measurement activity using the data, but rather to ensure that Qualified Entities receiving the data have shown appropriate evidence of their experience and capacity to measure and report results using such data; to protect patient privacy; and to make their methods and measurement results transparent and subject to public scrutiny. In our experience, organizations with experience in using claims data for public reporting have a good understanding of proper organizational conduct and know how to handle sensitive data. Given this, CMS should focus on penalties for the few that may be irresponsible rather than preemptively tying the hands of trustworthy entities.

Qualified Entities are required to share methods, measurement results, and the underlying data, including names of patients if requested, with providers of services and suppliers that will be included in the reports, prior to making the reports public. These provisions are important to ensuring the accuracy and fairness of public reports. We believe CMS should set up mechanisms for providers and suppliers to authenticate their identity and their own ability to protect data security before receiving information on patients. In addition, Qualified Entities must be allowed to set up requirements for any providers or suppliers requesting information to provide authentication of their identity and to document their own procedures for securely receiving and protecting data so that data and names are not sent to, or accessible to, someone other than the appropriate provider or supplier.

The proposed rule indicates that the Medicare claims data will be made available solely to Qualified Entities that will be using only claims data in their performance measures. However, much progress has been made in combining different data sources to produce a more comprehensive set of performance measures. Thus, it will sometimes be preferable to augment claims data with clinical data or other information to create a more dynamic database that can be drawn on to produce a more complete and accurate picture of provider performance. We strongly encourage CMS to expand the acceptable types of measures to include those that are derived from other data sources, including registries and electronic health records. We also suggest including not only physician data, but also reports that combine physician and hospital data. This is consistent with the direction of the Affordable Care Act, which encourages clinical integration and a focus on improving health outcomes. Performance measures should be responsive to these goals.

Medicare data also should be available for uses that extend beyond public reporting to include incorporation in provider rewards and consumer incentive programs. The law says that Qualified Entities receiving the data must produce public reports but it does not bar them from using these reports for other purposes, such as pay-for-performance, and does not bar allowing other organizations or individuals to use these reports for other purposes as well. We do not believe the proposed rule says otherwise, but we are concerned it might be interpreted

to limit the way Qualified Entities and others can use the results. We suggest CMS clarify that when reports are produced according to the rules, they can be used for other purposes in addition to public reporting.

Additionally, there may be instances where multiple organizations are requesting data for the same region. We believe CMS should allow different Qualified Entities to produce reports on the same region. Consumers can decide which information is most useful to their particular circumstances.

Finally, there are organizations that are only qualified to distribute performance reports to providers and the public. There are also organizations that are experienced at aggregating claims data and producing performance results. CMS should consider allowing organizations with the experience to produce performance results from claims data to be Qualified Entities as long as they provide aggregated results (e.g., numerators and denominators) to other qualified organizations that will distribute those results to providers and the public.

Balance the need for standardization with the need for innovation. Standardization of measures facilitates comparisons across different providers, thereby creating more useful and meaningful information. Giving preference to NQF-endorsed measures over other measures fosters standardization and ensures a level of confidence in the measures. However, despite the strong leadership of NQF and others in developing and endorsing measures, the current portfolio of nationally endorsed measures is too limited to meet the needs of consumers. Recognizing that performance measurement is an evolving field, it is critical that this rule permit innovation and flexibility in testing and/or using non-NQF endorsed measures. The proposed requirement for a formal comment and rule-making process unnecessarily adds burden and costs for CMS and Qualified Entities, and can dramatically slow improvement efforts. If a Qualified Entity can show that its use of an alternative measure meets any of the tests enumerated in the law, and if the Qualified Entity can provide evidence that stakeholders appropriate to judge its usefulness have determined it to be so, CMS should allow the data to be used for such a measure.

We also encourage CMS to apply the criteria in *The Patient Charter for Physician Performance Measurement, Reporting and Tiering Programs* (the "Patient Charter"), which is supported by a variety of stakeholders, used by many regional reporting initiatives, and incorporated into NCQA's Physician Hospital Quality Certification, in approving non-standardized measures.

Make the cost of acquiring Medicare data affordable for all Qualified Entities. The law says: "Data described in paragraph (3) shall be made available to a qualified entity under this subsection at a fee equal to the cost of making such data available [emphasis added]." We are concerned that, under the proposed rule as explained in the Supplementary information, CMS' charges for providing claims data to a Qualified Entity will be prohibitively expensive for many organizations, particularly highly qualified non-profit organizations, and that the basis for calculating the charges is not consistent with the law. The proposed rule estimates it will cost

\$200,000 to provide data on 2.5 million beneficiaries. That is substantially more than the current cost, from \$70,000 to \$107,000 as we understand it, to provide the same amount and type of data for research purposes.

We believe the intent of the law is that Qualified Entities be charged only CMS' incremental cost of "making data available," which we think is properly interpreted to refer to pulling the data and shipping it. We believe the Qualified Entities cannot be expected to pick up any portion of the cost of collecting the data and assembling it into an easily usable database. Indeed, CMS very likely will have other operational reasons to do that work. And we do not think any costs CMS incurs evaluating, monitoring, or giving technical assistance to Qualified Entities are costs of "making the data available." Rather, they are a component of the government's overall responsibility for operating parts of the health care system, and as a result of having data that is legally required to be made public.

We believe it is extremely important to avoid the unintended consequence of creating a pricing structure that will limit access to the data to only large, for-profit organizations. We also believe CMS may be able to reduce the costs it has to absorb in various ways, such as, eliminating or scaling back on technical assistance expenses (organizations needing such assistance could purchase the service in the private market) and streamlining its review process (NQF-endorsed measures that are used in the public report can be given "automatic" approval and the re-application process can be eliminated for organizations that have a problem-free record with their initial use of the data).

Furthermore, we recommend CMS consider a sliding scale based on the tax status of the Qualified Entity (e.g., charge non-profit organizations less). In its pricing, CMS should keep in mind that organizations conducting measurement activities are performing a function that assists CMS in carrying out its responsibility of improving quality and reducing costs in the healthcare system.

Do not limit the availability of Medicare claims data to areas where the Qualified Entity has claims data from other sources. The law requires Qualified Entities include in the evaluation of the performance of providers of services and suppliers claims data from non-Medicare sources along with Medicare claims data. However, the law does not require that the requesting Qualified Entity have these data from other sources in hand before receiving the Medicare claims data and, most importantly, does not require that the Qualified Entity have claims data from other sources for all areas where it will use Medicare claims.

The ACA requirement that the Qualified Entity have claims data from other sources serves two purposes. First, having such data even for a limited geographic area provides evidence of the Qualified Entity's experience of proper use and proper protection of the privacy and security of such data. Second, having such data will enable the Qualified Entity to do tests and assess and report on the extent to which using claims data from other sources affects measurement results compared to using Medicare data alone. For example, an important area of interest is having

reliable results. It is true that having non-Medicare claims data will increase sample sizes but having such data is not necessary to reliable reporting; requiring data from other sources is at best a crude way of trying to ensure reliability. Instead, CMS should focus on factors such as minimum number of observations, measure reliability, or confidence thresholds. Thus, the presence of non-Medicare data should not be a bright-line test and should not be required for all regions where the Qualified Entity is requesting Medicare claims data. Requiring non-Medicare claims data would be especially problematic for any Qualified Entity that intends to produce a national measure, since few if any Qualified Entities will have claims data for the entire U.S. Yet a national measurement program is more likely than many regional programs to have high visibility and also to serve areas where there is limited local quality improvement leadership.

Improve the efficiency of the process. Parts of the proposed rule can be streamlined for a more effective and efficient process. For example, Qualified Entities are required to re-apply with CMS upon change in measures or prototype report. In the case of measures, the proposed rule requires Qualified Entities to send new materials to CMS at least 90 days before its intended confidential release to providers of services and suppliers. The Qualified Entity cannot proceed with the new measures without approval. We propose removing the requirement that Qualified Entities apply for approval to change measures if they are switching to a standard measure. The law allows for the reporting of standard measures and having this step in place adds unnecessary costs and potentially delays reporting results.

There may be occasions when a Qualified Entity may need to change its prototype report. Following the proposed rules, the Qualified Entity would need to “send the new prototype report to CMS 90 days prior to its intended confidential release to providers of services and suppliers”. CMS should remove the requirement that Qualified Entities always apply for approval of changes to their report if the changes do not substantially change the report. For substantial changes, CMS should respond to the Qualified Entity in no more than 60 days. If CMS is unable to respond in this time frame, the Qualified Entity should be allowed to continue with public reporting.

Finally, we suspect certain oversight procedures will be more burdensome than beneficial. Although we support periodic auditing, we question the value and efficacy of site visits. These visits pose a large administrative cost and information can be gathered via other means. For those reasons, we recommend removing the site visit option.

On behalf of the millions of Americans represented by the undersigned organizations, thank you for your efforts to improve the quality and affordability of patient care. If you have any questions, please contact either of the Consumer-Purchaser Disclosure Project's co-chairs, William Kramer, Executive Director for National Health Policy for Pacific Business Group on Health, or Debra Ness, President of the National Partnership for Women & Families.

Sincerely,

AARP
American Benefits Council
American Hospice Foundation
The Boeing Company
Center for Medical Consumers
Childbirth Connection
Consumers' CHECKBOOK/Center for the Study of Services
Culinary Health Fund
The Empowered Patient Coalition
Greater Detroit Area Health Council
Health Action Council Ohio
HealthCare 21 Business Coalition
Health Policy Corporation of Iowa
Health Services Coalition
HR Policy Association
Indiana Employers Quality Health Alliance
Iowa Health Buyers Alliance
The Leapfrog Group
Lehigh Valley Business Coalition on Health Care
Maine Health Management Coalition
Massachusetts Group Insurance Commission
Mid-Atlantic Business Group on Health
Midwest Business Group on Health
National Business Coalition on Health
National Partnership for Women & Families
New Jersey Health Care Quality Institute
Niagara Health Quality Coalition
Northeast Business Group on Health
Pacific Business Group on Health
Puget Sound Health Alliance
PULSE of America
Silicon Valley Employers Forum
South Carolina Business Coalition on Health
St. Louis Area Business Health Coalition
Unite HERE Health
Virginia Business Coalition on Health
Wal-mart Stores, Inc.
Wyoming Business Coalition on Health

Appendix

Subpart G--Availability of Medicare Data for Performance Measurement

Sec. 401.701 Purpose and scope.

The regulations in this subpart implement section 1874(e) of the Social Security Act as it applies to the Centers for Medicare & Medicaid Services (CMS). The rules apply to Medicare data made available to qualified entities for the evaluation of the performance of providers of services and suppliers.

Sec. 401.702 Definitions.

(a) Qualified entity. A qualified entity is defined as a public or private entity that:

(1) 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, and

(2) Agrees to meet the requirements described in Section 1874(e) of the Social Security Act and meets the requirements at Sec. Sec. 401.703 through 401.710.

(b) Provider of services. A provider of services under this subpart is defined in the same manner as the identical term at section 1861(u) of the Social Security Act.

(c) Supplier. A supplier under this subpart is defined in the same manner as the identical term at section 1861(d) of the Social Security Act.

(d) Claims. Claims are itemized billing statements from providers of services and suppliers that, except in the context of Part D drug event date, request reimbursement for a list of services and supplies that were provided to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D (Prescription Drug) Event data.

(e) Standardized data extract. For purposes of this subpart, the standardized data extract is the subset of Medicare claims data that the Secretary would make available to qualified entities under this subpart.

(f) Beneficiary identifiable data. For the purposes of this subpart, beneficiary identifiable data is any data that contains the beneficiary name or beneficiary name and any other direct identifying factors, including, but not limited to, race, sex, age, or address.

(g) Encrypted data. For the purposes of this subpart, encrypted data is any data that does not contain the beneficiary name or any other direct identifying factors, but does include a unique beneficiary identifier that allows for the linking of claims without divulging the direct identifier of the beneficiary.

(h) Claims data from other sources. For purposes of this subpart, claims data from other sources means provider- or supplier-identified claims data that an entity has from its own operations or from providers of services, suppliers, private payers, all-payer databases, or other sources. An entity's having such data is relevant, along with other evidence of experience, with regard to its organization, operations, and governance.

(i) Cost of CMS making the data available. For purposes of this subpart, cost of making the data available means the incremental cost CMS incurs to provide the data to the requesting entity and does not include any cost CMS may incur in collecting or processing the data into a database from which the data can be drawn for release nor any cost CMS may incur screening requesting entities of monitoring the use of the data.

Sec. 401.703 Eligibility criteria for qualified entities.

(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, as applicable and appropriate to the proposed use :

(1) Organizational and governance criteria, including, to the extent necessary for the types of measurement the entity intends to carry out:

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

(A) Identifying an appropriate method to attribute a particular patient's services to specific providers of services and suppliers.

(B) Ensuring the use of approaches to ensure statistical validity such as a minimum number of observations or minimum denominator for each measure.

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

(D) Identifying methods for handling outliers.

(E) Correcting measurement errors and assessing measure reliability.

(F) Identifying appropriate peer groups of providers and suppliers for meaningful comparisons.

(ii) A business model that would cover the costs of performing the required functions, including the fee for the data.

- (iii) Successfully combining claims data from different payers to calculate performance reports.
- (iv) Designing, and continuously improving the format of performance reports on providers of services and suppliers.
- (v) Preparing an understandable description of the measures used to evaluate the performance of providers of services and suppliers so that consumers, providers of services and suppliers, health plans, researchers, and other stakeholders can assess performance reports.
- (vi) Implementing and maintaining a process for providers of services and suppliers identified in a report to review the report prior to publication and providing a timely response to provider of services and supplier inquiries regarding requests for data, error correction, and appeals.
- (vii) Establishing, maintaining, and monitoring a rigorous data privacy and security program, including disclosing to CMS any inappropriate disclosures of beneficiary identifiable information or HIPAA violations for the preceding 10-year period, and any corrective actions taken to address such issues.
- (viii) Accurately preparing performance reports on providers of services and suppliers and making performance report information available to the public in aggregate form, that is, at the provider of services or supplier level.

(2) Ability to combine Medicare claims data with claims data from other sources, ~~including demonstrating to the Secretary's satisfaction that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address many of the methodological concerns expressed by multiple stakeholders regarding the calculation of performance measures from a single payer source~~ so that it can carry out its responsibilities under Sec. 401.704 (a)(6).

(3) Documentation of rigorous data privacy and security policies including enforcement mechanisms.

(b) [Reserved]

Sec. 401.704 Operating and governance requirements for qualified entities.

(a) Submit to CMS a list of all measures it intends to calculate and report, the geographic areas it intends to serve, and the methods of creating and disseminating reports. This list must include the following information, as applicable and appropriate to the proposed use:

- (1) Name of the measure, and whether it is a standard or alternative measure,
- (2) Name of the measure developer/owner,
- (3) Measure specifications, including numerator and denominator,
- (4) The rationale for selecting each measure, including the relationship to existing measurement efforts and the relevancy to the population in the geographic area(s) the entity would serve, including:

- (i) A specific description of the geographic area or areas it intends to serve, and
 - (ii) A specific description of how each measure evaluates providers of services and suppliers on quality, efficiency, effectiveness, and/or resource use.
- (5) A description of the methodologies it intends to use in creating reports with respect to all of the following topics:
- (i) Attribution of beneficiaries to providers and/or suppliers,
 - (ii) Benchmarking performance data, including:
 - (A) Methods for creating peer groups,
 - (B) Justification of any minimum sample size determinations made,
- and
- (C) Methods for handling statistical outliers.
 - (iii) Risk adjustment.

(6) A description of—

(i) How it will evaluate and document the extent to which the usefulness to the public (including reliability, validity, and other factors) of reports it will be producing using the Medicare claims data might be affected by including or not including claims data from other sources, and

(ii) How it will combine with the Medicare claims data such claims data as it has from other sources, even if it has such data only for a limited number of the providers of services and suppliers whose performance it will be reporting on, if it concludes that using these claims data from other sources will enhance usefulness to the public.

(b) Submit to CMS a description of the process it would establish to allow providers of services and suppliers to view reports confidentially, request data, and ask for the correction of errors before the reports are made public.

(c) Submit to CMS a prototype report and a description of their plans for making the reports available to the public.

Sec. 401.705 The application process and requirements.

(a) Application deadline. Qualified entity applications must be submitted by March 31, 2012 and by the close of the first quarter of the calendar year each year thereafter.

(b) Selection criteria. To be approved as a qualified entity under this subpart, the applicant must meet the eligibility and operational and governance requirements, and fulfill all of the application requirements to CMS' satisfaction, agree to pay a fee equal to the cost of CMS making the data available, and execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart.

(c) Duration of approval. The 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 abide 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.

(d) Reporting period. Unless otherwise specified in its description of methods, ~~the a~~ qualified ~~entities~~ entity must produce reports on the performance of providers of services and suppliers annually beginning in the calendar year after they are approved by CMS.

(e) The distribution of data. Once a qualified entity is approved by CMS under this subpart, it would be required to pay a fee equal to the cost of CMS making this data available. After the qualified entity pays the fee, CMS would release claims data to the qualified entity.

(1) CMS would release standardized extracts of encrypted data from Medicare parts A and B claims data, and D drug event data for the most recent three years of data available at that time. ~~The data would be limited to the geographic spread of the qualified entity's other claims data as determined by CMS.~~

(2) After the first year of participation, CMS would provide qualified entities with the most recent additional year of data on a yearly basis. Qualified entities would be required to pay a fee equal to the cost of CMS making this data available before CMS would release the most recent year of additional data to the qualified entity.

(f) Re-application. Qualified entities 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. To reapply a qualified entity would need to submit to CMS documentation of any changes to what was included in their original application. 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.

Sec. 401.706 Updates to plans submitted as part of the application process.

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

(1) Its list of proposed measures, the qualified entity must send all the information referenced in Sec. 401.704(a) for the new measure to CMS at least 90 days prior to its intended confidential release to providers of services and suppliers.

(2) Its proposed prototype report, 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, 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.

(b) The qualified entity 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 without first obtaining CMS approval.

~~—(c) If the amount of claims data from other sources available to a qualified entity decreases, the qualified entity must immediately inform CMS and submit documentation that the remaining claims data from other sources is sufficient to address the methodological concerns regarding sample size and reliability. Under no circumstances may a qualified entity issue a report, use a measure, or share a report after this point.~~

~~—(1) If CMS determines that the remaining claims data is not sufficient, the qualified entity would have 60 days to acquire new data and submit new documentation to CMS. If after 60 days, the qualified entity does not have access to new data or if 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.~~

Sec. 401.707 Ensuring the privacy and security of data.

(a) Qualified entities must comply with the data requirements in the data use agreement (DUA) with CMS. The DUA would require the qualified entity to maintain privacy and security protocols throughout the duration of their agreement with CMS and would ban the use of data for purposes other than those referenced in this subpart. The DUA would also prohibit the use of unsecured telecommunications to transmit CMS data and would require disclosure of the circumstances under which CMS data would be stored and transmitted.

(b) Qualified entities must inform each beneficiary whose beneficiary identifiable data has been or is reasonably believed to have been inappropriately accessed, acquired, or disclosed pursuant to the DUA.

Sec. 401.708 Selection and use of performance measures.

(a) Standard measure. A standard measure is defined as a measure that can be calculated from the standardized extracts of Medicare Parts A and B claims, and Part D drug event data that:

(1) Meets one of the following criteria:

(i) Endorsed by the entity with a contract under section 1890(a) of the Social Security Act;

(ii) Time-limited endorsed by the entity with a contract under Section 1890(a) of the Social Security Act until such time as the full endorsement status is determined;

(iii) Developed pursuant to section 931 of the Public Health Service Act; or

(iv) Can be calculated, in whole or in part, using from standardized extracts of Medicare parts A or B claims or part D drug event data, was adopted through notice and comment rulemaking and is currently being used in CMS programs that include quality measurement.

(2) Is used 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.

(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-using the standardized extracts of Medicare Parts A and B claims, and Part D drug event data ~~that if~~:

(i) ~~Has been found by t~~The Secretary determines through a notice and comment rulemaking process that its use would, 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, such determination to be based on—

(A) Information submitted by the requesting entity,

(B) Information submitted by one or more other parties reporting on consultations with members of the public, including consumers and providers of services and suppliers of types whose performance would be measured, or

(C) Information collected through a notice and comment rulemaking process,

~~and,~~

(ii) ~~Is~~The measure will be 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) An alternative measure may be used up until the point that a standard measure or measures become available such that the use of the alternative measure is no longer more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use than if the alternative measure were not used, 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 the Secretary to continue using the alternative measure.

(3) To submit an alternative measure for consideration for use in the following calendar year an entity must submit the following by May 31st:

(i) The name of the alternative measure.

(ii) The name of the alternative measure's developer or owner if a specific developer or owner is known.

(iii) Detailed specifications for the alternative measure.

(iv) ~~Information demonstrating how~~Evidence that use of the alternative measure ~~is would be~~ more valid, reliable, cost-effective, relevant responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures than if the measure were not used.

Sec. 401.709 Provider of services and supplier requests for error correction.

(a) Qualified entities must announce on a public website provided by HHS, or in notifications to major organizations that represent types of providers of services and suppliers that have been evaluated by the entity, the availability of reports for confidentially review, and must share-make available measures, measurement methodologies, and measure results ~~with to evaluated~~ providers of services and suppliers at least 30 business days prior to making reports public. The 30 days begins on the date on which qualified entities send the confidential reports to providers of services and suppliers.

(b) Qualified entities must allow providers of services and suppliers at least 10 business days after receipt of a report to make a request for the data.

(c) Qualified entities must allow providers of services and suppliers at least 10 business days after receipt of the data to make a request for error correction.

(d) If a qualified entity receives a request for beneficiary names from a provider of services or supplier, the qualified entity must 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 Sec. 401.710(d).

(e) Qualified entities must inform providers of services and suppliers that reports would be made public, including information related to the status of any data or error correction requests, after a specified date (at least 30 business days after the report was originally shared with providers of services and suppliers), regardless of the status of any requests for error correction.

(f) If a provider of services or supplier still has a data or error correction request outstanding at the time of making the reports public, the qualified entity must, if feasible, post publicly the name of the appealing provider and the category of the appeal request.

(g) Prior to sending measure results, data used in calculating the results, beneficiary names, or other information to any provider of services or supplier, a qualified entity may require that the requesting provider of services or supplier, according to standards and procedures specified by the qualified entity, document and authenticate the identity of the requesting provider of services or supplier, its legal right to see the requested data under applicable laws protecting patient privacy, and a secure communication process the provider of services or supplier will provide for transmission of the requested information.

Sec. 401.710 Monitoring and sanctioning of qualified entities.

(a) CMS would monitor and assess the performance of qualified entities using the following methods:

(1) Audits

(2) Submission of documentation of data sources and quantities of data upon the request of CMS and/or site visits

(3) Analysis of specific data reported to CMS by qualified entities through annual reports, as described in paragraph (b) of this section, and reports on inappropriate disclosures or uses of beneficiary identifiable data, as described in paragraph (c) of this section.

(4) Analysis of complaints from beneficiary-beneficiaries and/or providers of services or suppliers. ~~complaints~~

(b) Qualified entities must provide annual reports to CMS containing information related to:

(1) General program adherence, including:

(i) The approximate number of Medicare and private claims combined.

(ii) The approximate percent of the overall market share the number of claims represents in the ~~qualified entity's geographic~~ area included in the qualified entity's reports.

(iii) The number of measures calculated.

(iv) The approximate number of providers of services and suppliers profiled by type of provider and supplier.

(v) A measure of public use of the reports.

(2) The provider^s of services and suppliers data sharing, error correction, and appeals process, including:

- (i) The number of providers of services and suppliers requesting claims data.
- (ii) The number of requests for claims data fulfilled.
- (iii) The number of error corrections.
- (iv) The type(s) of problem(s) leading to the request for error correction.
- (v) The time to acknowledge the request for data or error correction.
- (vi) The time to respond to the request for error correction.
- (vii) The number of requests for error correction resolved.

(c) Qualified entities must inform CMS of inappropriate disclosures or uses of beneficiary identifiable data pursuant to the requirements in the DUA.

(d) CMS may take the following actions against qualified entities if it is determined that they are violation of any of the requirements of the qualified entity program, regardless of how CMS learns of the violation:

- (1) Provide a warning notice, which indicates that future deficiencies could lead to termination, to the qualified entity of the specific concern
- (2) Request a corrective action plan (CAP) from the qualified entity
- (3) Place the qualified entity on a special monitoring plan
- (4) Terminate the qualified entity

Sec. 401.711 Termination of qualified entities.

(a) Grounds for terminating a qualified entity agreement. CMS may terminate an agreement with a qualified entity if the qualified entity:

- (1) Engages in one or more serious violations of the requirements of the qualified entity program.
- (2) Fails to completely and accurately report information to CMS or fails to make timely corrections to reported performance information per providers of services and supplier requests for such correction.
- (3) Fails to submit an approvable corrective action plan (CAP), fails to implement an approved CAP, or fails to demonstrate improved performance after the implementation of a CAP.
- (4) Improperly uses or discloses claims information received from CMS in violation of the requirements of the regulations in this subpart.
- (5) Based on their reapplication, no longer meets the requirements in this subpart.

(b) Return of CMS data upon voluntary or involuntary termination from the qualified entity program:

(1) If a qualified entity's agreement with CMS is terminated by CMS, it must immediately upon receipt of notification of such termination commence returning or destroying any and all CMS data (and any derivative files). In no instance should this process exceed 30 days.

(2) If a qualified entity voluntarily terminates participation in the program, it must return to CMS, or destroy, any and all CMS data in its possession within 30 days notifying CMS of its intent to end participation.

Sec. 401.711 Applicability of this subsection

The provisions of subsection 1874 (e) of the Social Security Act and of these regulations implementing such subsection do not affect or limit in any way other provisions under which Medicare claims data may be released, or have been released, including, for example, release of data for research purposes or release of data on hospitals.