identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed in accordance with the DUA.

(c) Contractor(s) must report to the qualified entity whenever there is an incident where beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed.

§401.715 Selection and use of performance measures.

(a) *Standard measures.* A standard measure is a measure that can be calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data and meets the following requirements:

(1) Meets one of the following criteria:

(i) Is endorsed by the entity with a contract under section 1890(a) of the Social Security Act.

(ii) Is 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) Is developed under section 931 of the Public Health Service Act.

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

(v) Is endorsed by a CMS-approved consensus-based entity. CMS will approve organizations as consensus-based entities based on review of documentation of the consensus-based entity's measure approval process. To receive approval as a consensus-based entity, an organization must submit information to CMS documenting its processes for stakeholder consultation and measures approval; an organization will only receive approval as a consensus-based entity if all measure specifications are publically available. An organization will retain CMS acceptance as a consensus-based entity for 3 years after the approval date, at which time CMS will review new documentation of the consensus-based entity's measure approval process for a new 3-year approval.

(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 a measure that is not a standard measure, but that can be calculated in full, or in part, from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data, and that meets one of the following criteria:

(i) *Rulemaking process:* Has been found by the Secretary, through a notice-and comment-rulemaking process, 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, and is used by a qualified entity in a manner that follows the measure specifications as adopted through notice-and-comment rulemaking, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(ii) *Stakeholder consultation approval process:* Has been found by the Secretary, using documentation submitted by a qualified entity that outlines its consultation and agreement with stakeholders in its community, to be more valid, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as submitted, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources. If a CMS decision on approval or disapproval of alternative measures submitted using the stakeholder consultation approval process is not forthcoming within 60 days of submission of the measure by the qualified entity, the measure will be deemed approved. However, CMS retains the right to disapprove a measure if, even after 60 days, we find it to not be ''more valid,

reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource'' than a standard measure.

(2) An alternative measure approved under the process at paragraph (b)(1)(i) of this section may be used by any qualified entity. An alternative measure approved under the process at paragraph (b)(1)(ii) of this section may only be used by the qualified entity that submitted the measure for consideration by the Secretary. A qualified entity may use an alternative measure up until the point that an equivalent standard measure for the particular clinical area or condition becomes available at which point the qualified entity must switch to the standard measure within 6 months or submit additional scientific justification and receive approval, via either paragraphs (b)(1)(i) or (b)(1)(ii) of this section, from the Secretary to continue using the alternative measure.

(3) To submit an alternative measure for consideration under the notice-and-comment-rulemaking process, for use in the calendar year following the submission, an entity must submit the following information by May 31st:

(i) The name of the alternative measure.

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

(iii) Detailed specifications for the alternative measure.

(iv) Evidence that use of the alternative measure would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures.

(4) To submit an alternative measure for consideration under the documentation of stakeholder consultation approval process described in paragraph (b)(1)(ii) of this section, for use once the measure is approved by the Secretary, an entity must submit the following information to CMS:

(i) The name of the alternative measure.

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

(iii) Detailed specifications for the alternative measure.

(iv) A description of the process by which the qualified entity notified stakeholders in the geographic region it serves of its intent to seek approval of an alternative measure. Stakeholders must include a valid cross representation of providers, suppliers, payers, employers, and consumers.

(v) A list of stakeholders from whom feedback was solicited, including the stakeholders' names and roles in the community.

(vi) A description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure.

(vii) Unless CMS has already approved the same measure for use by another qualified entity, no new scientific evidence on the measure is available, and the subsequent qualified entity wishes to rely upon the scientific evidence submitted by the previously approved applicant, an explanation backed by scientific evidence that demonstrates why the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure.

§ 401.717 Provider and supplier requests for error correction.

(a) A qualified entity must confidentially share measures, measurement methodologies, and measure results with providers and suppliers at least 60 calendar days before making reports public. The 60 calendar days begin on the date on which qualified entities send the confidential reports to providers and suppliers. A qualified entity must inform providers and suppliers of the date the reports will be made public at least 60 calendar days before making the reports public.

(b) Before making the reports public, a qualified entity must allow providers and suppliers the opportunity to make a request for the data, or to make a request for error correction, within 60 calendar days after sending the confidential reports to providers or suppliers.

(c) During the 60 calendar days between sending a confidential report on measure results and releasing the report to the public, the qualified entity must, at the request of a provider or