

those aimed at improving patient safety, quality of care, or population health, including the development of new models of care, the development of means to expand coverage and improve access to healthcare, the development of means of reducing healthcare disparities, and the development or improvement of methods of payment or coverage policies.

(B) Activities falling under paragraph (2) of the definition of “health care operations” under 45 CFR 164.501: Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.

(C) Activities that qualify as “fraud and abuse detection or compliance activities” under 45 CFR 164.506(c)(4)(ii).

(D) Activities that qualify as “treatment” under 45 CFR 164.501.

(ii) All other uses and disclosures of such data and/or such non-public analyses must be forbidden except to the extent a disclosure qualifies as a “required by law” disclosure as defined at 45 CFR 164.103.

(2) The authorized user is prohibited from using or disclosing the data or non-public analyses for marketing purposes as defined at § 401.703(s).

(3) The authorized user is required to ensure adequate privacy and security protection for such data and non-public analyses. At a minimum, regardless of whether the authorized user is a HIPAA covered entity, such protections of beneficiary identifiable data must be at least as protective as what is required of covered entities and their business associates regarding protected health information (PHI) under the HIPAA Privacy and Security Rules. In all cases, these requirements must be imposed for the life of such beneficiary identifiable data or non-public analyses and/or any derivative data, that is until all copies of such data or non-public analyses are returned or destroyed. Such duties must be written

in such a manner as to survive termination of the QE DUA, whether for cause or not.

(4) Except as provided for in paragraph (d)(5) of this section, the authorized user must be prohibited from re-disclosing or making public any such data or non-public analyses.

(5)(i) At the qualified entity’s discretion, it may permit an authorized user that is a provider as defined in § 401.703(b) or a supplier as defined in § 401.703(c), to re-disclose such data and non-public analyses as a covered entity will be permitted to disclose PHI under 45 CFR 164.506(c)(4)(i), under 45 CFR 164.506(c)(2), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a “required by law” disclosure.

(6) Authorized users who/that receive the beneficiary de-identified combined data or Medicare data as contemplated under § 401.718 are contractually prohibited from linking the beneficiary de-identified data to any other identifiable source of information, and must be contractually barred from attempting any other means of re-identifying any individual whose data is included in such data.

(7) The QE DUA must bind authorized user(s) to notifying the qualified entity of any violations of the QE DUA, and it must require the full cooperation of the authorized user in the qualified entity’s efforts to mitigate any harm that may result from such violations, or to comply with the breach provisions governing qualified entities under this subpart.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44479, July 7, 2016]

§ 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

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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 expla-

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nation 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.

§ 401.716 Non-public analyses.

(a) *General.* So long as it meets the other requirements of this subpart, and subject to the limits in paragraphs (b) and (c) of this section, the qualified entity may use the combined data to create non-public analyses in addition to performance measures and provide or sell these non-public analyses to authorized users (including any contractors or business associates described in the definition of authorized user).

(b) *Limitations on a qualified entity.* In addition to meeting the other requirements of this subpart, a qualified entity must comply with the following limitations as a pre-condition of dissemination or selling non-public analyses to an authorized user:

(1) A qualified entity may only provide or sell a non-public analysis to a health insurance issuer as defined in § 401.703(l), after the health insurance issuer or a business associate of that health insurance issuer has provided the qualified entity with claims data that represents a majority of the health insurance issuer's covered lives, using one of the four methods of calculating covered lives established at 26 CFR 46.4375–1(c)(2), for the time period and geographic region covered by the issuer-requested non-public analyses. A qualified entity may not provide or sell a non-public analysis to a health insurance issuer if the issuer does not have any covered lives in the geographic region covered by the issuer-requested non-public analysis.

(2) Analyses that contain information that individually identifies one or more beneficiaries may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) when both of the following conditions are met:

(i) The analyses only contain identifiable information on beneficiaries with whom the provider or supplier have a patient relationship as defined at § 401.703(r).