

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 supplier and with appropriate privacy and security protections, release the Medicare claims data and beneficiary names to the provider or supplier. Qualified entities may only provide the Medicare claims and/or beneficiary names relevant to the particular measure or measure result the provider or supplier is appealing.

(d) A qualified entity must inform providers and suppliers that reports will be made public, including information related to the status of any data or error correction requests, after the date specified to the provider or supplier when the report is sent for review and, if necessary, error correction requests (at least 60 calendar days after the report was originally sent to the providers and suppliers), regardless of the status of any requests for error correction.

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

(f) A qualified entity must comply with the following requirements before disclosing non-public analyses, as defined at § 401.716, which contain information that individually identifies a provider or supplier:

(1) A qualified entity must confidentially notify a provider or supplier that non-public analyses that individually identify the provider or supplier are going to be released to an authorized

user at least 65 calendar days before disclosing the analyses. This confidential notification must include a short summary of the analyses (including the measures calculated), the process for the provider or supplier to request the analyses, the authorized users receiving the analyses, and the date on which the qualified entity will release the analyses to the authorized user.

(2) A qualified entity must allow providers and suppliers the opportunity to opt-in to the review and correction process as defined in paragraphs (a) through (e) of this section, anytime during the 65 calendar days. If a provider or supplier chooses to opt-in to the review and correction process more than 5 days into the notification period, the time for the review and correction process is shortened from 60 days to the number of days between the provider or supplier opt-in date and the release date specified in the confidential notification.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44481, July 7, 2016]

§ 401.718 Dissemination of data.

(a) *General.* Subject to the other requirements in this subpart, the requirements in paragraphs (b) and (c) of this section and any other applicable laws or contractual agreements, a qualified entity may provide or sell combined data or provide Medicare data at no cost to authorized users defined at § 401.703(b), (c), (m), and (n).

(b) *Data*—(1) *De-identification.* Except as specified in paragraph (b)(2) of this section, any data provided or sold by a qualified entity to an authorized user must be limited to beneficiary de-identified data. De-identification must be determined based on the de-identification standards for HIPAA covered entities found at 45 CFR 164.514(b).

(2) *Exception.* If such disclosure will be consistent with all applicable laws, data that individually identifies a beneficiary may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) with whom the identifiable individuals in such data have a current patient relationship as defined at § 401.703(r).

(c) *Data use agreement between a qualified entity and an authorized user.* A

qualified entity must contractually require an authorized user to comply with the requirements in §401.713(d) prior to providing or selling data to an authorized user under §401.718.

[81 FR 44481, July 7, 2016]

§401.719 Monitoring and sanctioning of qualified entities.

(a) CMS will monitor and assess the performance of qualified entities and their contractors 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 beneficiaries and/or providers or suppliers.
- (b) A qualified entity must provide annual reports to CMS containing information related to the following:
 - (1) General program adherence, including the following information:
 - (i) The number of Medicare and private claims combined.
 - (ii) The percent of the overall market share the number of claims represent in the qualified entity's geographic area.
 - (iii) The number of measures calculated.
 - (iv) The number of providers and suppliers profiled by type of provider and supplier.
 - (v) A measure of public use of the reports.
 - (2) The provider and supplier data sharing, error correction, and appeals process, including the following information:
 - (i) The number of providers 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 amount of time to acknowledge the request for data or error correction.

(vi) The amount of time to respond to the request for error correction.

(vii) The number of requests for error correction resolved.

(3) Non-public analyses provided or sold to authorized users under this subpart, including the following information:

(i) A summary of the analyses provided or sold, including—

(A) The number of analyses.

(B) The number of purchasers of such analyses.

(C) The types of authorized users that purchased analyses.

(D) The total amount of fees received for such analyses.

(E) QE DUA or non-public analyses agreement violations.

(ii) A description of the topics and purposes of such analyses.

(iii) The number of analyses disclosed with unresolved requests for error correction.

(4) Data provided or sold to authorized users under this subpart, including the following information:

(i) The entities who received data.

(ii) The basis under which each entity received such data.

(iii) The total amount of fees received for providing, selling, or sharing the data.

(iv) QE DUA violations.

(c) A qualified entity must inform CMS of inappropriate disclosures or uses of beneficiary identifiable data under the DUA.

(d) CMS may take the following actions against a qualified entity if CMS determines that the qualified entity violated any of the requirements of this subpart, regardless of how CMS learns of a violation:

(1) Provide a warning notice to the qualified entity of the specific concern, which indicates that future deficiencies could lead to termination.

(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.

(5) In the case of a violation, as defined at §401.703(t), of the CMS DUA or