

## **CAREQUALITY DISPUTE**

### **FINAL RESOLUTION (REDACTED)**

Epic – Particle Health Dispute

October 3, 2024

#### ***I. INTRODUCTION***

##### **Dispute Resolution Process**

Carequality has a defined Dispute Resolution Process to address conflicts, potential violations, and differences in interpretation of Carequality requirements between framework Implementers and Connections.

The Dispute Resolution Process includes a requirement for an informal conference between the parties to attempt to resolve the issues. If unresolved, an Implementer can request an issue be escalated to a Dispute and formally go through the Dispute Resolution Process. Once a Dispute is received by Carequality, a dispute panel made up of members from the Carequality community is assembled as set forth in the Dispute Resolution Process. The Dispute Panel holds one or more confidential meetings with the involved parties and strives to develop an appropriate and equitable Recommendation for Resolution to the Steering Committee. The Steering Committee then reviews the Dispute Panel's Recommendation for Resolution and available evidence and either requests further review from the Dispute Panel or issues the Steering Committee Resolution. The parties to the Dispute have the right to appeal the Steering Committee Resolution to the Advisory Council.

All additional details of the Dispute Resolution Process are set forth in the [Carequality Dispute Resolution Process](#).

##### **Background/Timeline Summary**

On March 21, [2024], Epic filed a Dispute against Particle Health alleging: 1) that Particle Health inappropriately claimed a Treatment Permitted Purpose for entities that do not support a treatment use case, and 2) that Particle Health built a Carequality gateway that masks the identity of organizations requesting medical records (see Section II – Epic's Claims and Requested Relief). Thereafter, Epic confirmed that several Particle Health customers were the focus of the filed Dispute, including [Connection 1], [Connection 2], and [Connection 3]<sup>1</sup> and provided a Pre-Dispute Statement containing

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<sup>1</sup> Redaction Note: In the redacted version, Connection names have been replaced with generic identifiers since the

additional information. On May 3, Particle Health submitted a response to Epic's claims and filed its own Dispute against Epic alleging discriminatory conduct and improper suspensions of Particle Connections without initiating a dispute or identifying the bases for such suspensions.

Beginning on April 22, 2024, the Dispute Resolution Subcommittee met to identify members for the 3-person Dispute Panel. After being informed of the composition of the Dispute Panel, one of the parties objected. The Steering Committee considered this objection at its May 15 meeting and ratified the composition of the Panel, which included [Panelist 1] ([Implementer 1]), [Panelist 2] ([Implementer 2]), and [Panelist 3] ([Implementer 3]).<sup>2</sup>

On May 21, May 22, May 31, June 6, and June 10, the Dispute Panel met to discuss the materials provided by the parties, formulate questions and requests for additional materials, and prepare for the Dispute Panel Meeting. On June 6 and June 14, the Panel sent both parties questions and requests for supplemental information. Particle Health provided information in response to the Dispute Panel's requests on June 11 and June 19. Epic provided information in response to the Dispute Panel's requests on June 12 and June 19. On June 20, the first Dispute Panel Meeting took place.

On June 28, July 10, and July 19, the Dispute Panel met to discuss the first Dispute Panel Meeting, the materials received from the parties, and to confer with privacy and technical SMEs.<sup>3</sup> The Dispute Panel Meeting and guidance from both the technical and privacy SMEs raised additional questions from the Dispute Panel. On July 18 and July 19, the Panel sent both parties questions and requests for supplemental information. Both parties provided information in response to the Dispute Panel's requests on July 26. Given that questions remained, specifically around Particle Health's customer [Connection 3], the Dispute Panel requested a Second Dispute Panel Meeting, which was held on July 23. Following the Second Dispute Panel meeting, the Panel sent Particle Health follow-up questions and requests for supplemental information on August 1. Particle Health provided information in response to the Dispute Panel's requests on August 6.

On July 26, July 31, August 7, and August 9, the Dispute Panel met to continue its discussions. On August 14, the Dispute Panel provided their written Recommendations for Resolution to the Steering Committee and then presented those Recommendations for Resolution to the Steering Committee on August 27. The Dispute Panel's evaluation of the claims set forth by the parties and recommendations to the Steering Committee for resolution were adopted and accepted by the Steering Committee on August 29 and are summarized in this document.

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Connections have not consented to the release of the Final Resolution.

<sup>2</sup> Redaction Note: In the redacted version, the panelists' names and the organizations that they represent have been replaced with generic identifiers.

<sup>3</sup> Redaction Note: SMEs are subject matter experts.

## **Standard for Review**

### *Materials Reviewed and Considered*

When considering the Disputes between the parties and the Dispute Panel's Recommendations for Resolution, the Steering Committee considered the requirements of the Carequality Connected Agreement (CCA), the Carequality Connection Terms, the Carequality Framework Policies, and the Query-Based Document Exchange Implementation Guide. As permitted in the Dispute Resolution Process, the Dispute Panel also requested additional materials and information from both parties prior to and after both Dispute Panel Meetings to help inform its recommendations to the Steering Committee. See Appendix 1 for a list of the key materials provided to and considered by the Steering Committee in coming to its findings and Resolution.

### *Use of Subject Matter Experts*

The Dispute Resolution Process states that the Dispute Panel will have access to Subject Matter Experts (SMEs), including but not limited to Carequality legal counsel, to advise on relevant matters. The Dispute Panel engaged two privacy SMEs who have an extensive background in policy, legal, and operational interpretations of HIPAA and related privacy regulations.

The Dispute Panel also engaged a technical SME who has an extensive background and experience with the Carequality Directory and technical requirements.

Each SME signed a Confidentiality Agreement. Throughout the process, Carequality staff and Carequality in-house and external legal counsel have assisted the Panel and the Steering Committee with the Dispute Resolution Process where requested by the Panel or the Steering Committee Chair.

### *Claims of Inappropriate Treatment*

When considering Epic's claims surrounding the appropriate use of the Treatment Purpose of Use, the Panel and the Steering Committee reviewed the definition of "Treatment" in HIPAA since that is the current Permitted Purpose under the applicable Carequality documents. "Treatment" as defined by HIPAA (45 CFR 164.501) means "the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another." "Health care" is in turn defined by HIPAA (45 CFR 160.103) as "care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and (2) Sale or dispensing of a drug, device,

equipment, or other item in accordance with a prescription.”

### *Development of Findings and Resolution*

The Dispute Resolution Process states that to the extent necessary to address any issues identified through the Dispute, the Dispute Panel has the authority to recommend, and the Steering Committee has the authority to adopt corrective action plans with required timelines for implementation of such plans, suspension of a party’s ability to participate in Carequality activities, or termination of a party’s status as an Implementer or Carequality Connection. Corrective action plans implemented by the Steering Committee are limited to those steps necessary to restore a party to compliance with the CCA, Connection Terms, Framework Policies or other Carequality Elements. The Steering Committee has not and may not impose any monetary penalties on any party or otherwise require the provision of funds or in-kind support by one party to the other.

## **II. EPIC’S CLAIMS AND REQUESTED RELIEF**

In Epic’s Pre-Dispute Statement, dated April 24, 2024 (Attachment 1)<sup>4</sup> and Epic’s Statement in Response to Particle Health (Attachment 4), Epic states the following claims against Particle Health:

- Particle Health inappropriately claimed a Treatment Permitted Purpose for entities that do not support a treatment use case, including for [Connection 1], [Connection 2], and [Connection 3] in violation of Section 3.1 of the Carequality Framework Policies, Section 13 of the CCA, and Section 12 of the Carequality Connection Terms.
- Particle Health built a Carequality gateway that masks the identity of organizations requesting medical records.
  - Particle Health has added thousands of entries to the Carequality directory that were duplicative of the entries of Epic and other Implementers in violation of Section 15.1 of the CCA and Section 2.2 of the Connection Terms.
  - Particle Health has failed to identify the End Users of its connections as required by Section 15.3 of the Carequality Connected Agreement and Section 3.2.1 of the Carequality Framework Policies.
  - Particle Health has failed to remove “On Behalf Of” (OBO) designations for many entries after having been notified of objections from Epic and Epic Community members in a timely manner, in violation of Section 3.2.1.3 of the Carequality Framework Policies.

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<sup>4</sup> Release Note: While the Final Resolution references attachments, which are listed in Appendix 1, the attachments contain confidential information and are not being released with the Final Resolution.

- Particle Health has failed to provide information necessary to evaluate potential HIPAA breaches in violation of Sections 6 and 11 of the CCA and Sections 4 and 10 of the Connection Terms.
- Particle Health and its customers have used Carequality to retrieve more than 7,000,000 medical records from Epic’s customers, while sharing back only 100,000 records. This 70:1 exchange ratio violates Carequality’s reciprocity requirements as outlined in Section 3.2 (Full Participation) and 3.4. (Data Sufficiency and Integrity) of the Carequality Framework Policies.
- Particle Health avoids responsibility for its customers’ actions.

Epic has requested the following relief:

- Deem Particle Health a Carequality Implementer not in good standing and suspend their ability to onboard new connections.
- Establish a process with appropriate oversight that Particle Health can follow to return to good standing as a Carequality Implementer and re-onboard their current customers.
- Require Particle Health to provide a detailed accounting of disclosures for each patient record taken using Particle’s generic gateway.
- Require Particle Health to delete and confirm deletion of data obtained through Carequality in violation of HIPAA and Carequality policies.
- Require Particle Health to submit corrective action plans for approval and oversight in order to remain an Implementer. The Steering Committee should meet weekly until a resolution path is defined.
- Deny Particle Health’s requested relief.

### ***III. PARTICLE’S CLAIMS AND REQUESTED RELIEF***

In Particle’s Statement in Response to Epic, received May 3, 2024 (Attachment 2), and its Dispute Statement, received May 3, 2024 (Attachment 3), Particle states the following claims against Epic, and in response to Epic’s claims against Particle:

- In response to Epic’s claims:
  - The Particle Health gateway referenced in Epic’s claims did not mask the identity of any of Particle Health’s connections.
    - Particle Health complied with the rules of Carequality and has always clearly identified the receiving party.

- Particle Health, at Epic’s request, changed the structure of its queries to comply with the structure requested by Epic.
  - Particle Health has not misrepresented the nature of its connections’ treatment use.
    - Epic’s challenge to [Connection 3]’s treatment purpose of use is inaccurate.
    - Particle initially argued that Epic’s statements misrepresented the nature and history of Particle Health’s relationship with [Connection 1]. After viewing the video evidence that Epic provided regarding [Connection 1], Particle determined that it had been misled by [Connection 1] and terminated them as a customer.
  - Particle Health did not create misleading entries on the Carequality Directory.
  - Particle Health has not improperly withheld any information from Epic.
- Claims asserted against Epic:
  - In violation of numerous Carequality rules, Epic has suspended its responses to treatment queries made by several Particle Connections, including providers, without initiating a dispute or identifying the bases for such suspensions.
  - Epic has violated Carequality’s anti-discrimination rules by (i) suspending its responses to treatment queries made by Particle customers based on undisclosed and arbitrary criteria that are not universally applied; and (ii) refusing to timely onboard new Particle Connections, while onboarding Connections of other Implementers.
  - Epic has circumvented Carequality’s dispute resolution process by creating its own remedies for perceived wrongs, and by making false and misleading public statements that it has refused to correct.

Particle Health has requested the following relief:

- Have Carequality issue a press release indicating that Particle Health is a Carequality Implementer in good standing and that it has followed the rules of Carequality;
- Require Epic to resume responding to all queries of Particle Connections that it has improperly suspended;
- Deem Epic’s implementation of its policies and protocols for responding to

queries in violation of Carequality’s non-discrimination rules;

- Require Epic to revise its Phonebook Support Policy and other Procedures so its onboarding requirements are consistent with Carequality Rules, including the anti-discrimination provisions;
- Require Epic to work collaboratively with Particle to establish a better process for Carequality Implementers to onboard their customers without fear of retaliation so that Epic cannot improperly refuse to respond;
- Deem all [Connection 3] queries, including queries in connection with the [ ] program, to be “treatment” queries;
- Appoint a Particle representative to the Carequality Steering Committee; and
- Deny all of Epic’s claims.

#### ***IV. FINDINGS AND RESOLUTION***

##### **1. [Connection 1]:**

- a. **Findings:** The Panel was provided with a video of a sales meeting between [Connection 1] and a potential customer. In the video, [Connection 1] was selling its solution to potential customers as a way to screen individuals who may have legal claims. While [Connection 1] did reference having a staff of physicians who review records, this was not a focus of the presentation. In addition, as part of the sales demo, [Connection 1] queried for records for one of the potential customers based on the potential customer’s authorization – not in connection with the potential customer seeking treatment. While it is not clear in the video whether the request was for treatment or made through Carequality, given the context and speed of response, it is assumed that this query was made by asserting the treatment purpose through Carequality.

On June 27, Particle notified the Panel that “[s]ince receiving the [Connection 1] video from Epic last Monday, we have now closely reviewed the video several times and determined that the video strongly indicates that, at least in certain instances, [Connection 1] made queries for non-treatment purposes in violation of [Connection 1]’s contractual obligations to Particle, as well as contrary to additional representations that [Connection 1] made to Particle. As a result, Particle has now terminated its contractual relationship with [Connection 1] and asked [Connection 1] to destroy any records queried on Carequality.” Based on Particle’s termination of [Connection 1], [Connection 1] is no longer a Carequality Connection. In the same June 27 communication, Particle informed the Panel that [Connection 1] represented it has HIPAA-compliant authorizations for each request that it made through Carequality. (See Attachment 7). The Steering Committee adopts these findings.

b. **Resolution:**

- i. **[Connection 1] is not permitted to participate in Carequality for 12 months for any Permitted Purpose.** If [Connection 1] attempts to join Carequality after 12 months, it must secure approval from the Steering Committee prior to joining. This exclusion and subsequent approval requirement are applicable to [Connection 1] as well as any successor entity or any entity owned or operated by any of the owners of [Connection 1].
- ii. **Within 20 business days of the Steering Committee Resolution, Particle will demand that [Connection 1]: (i) provide to each health care provider from whom it received data a notification that it received data through Carequality based on a query that asserted treatment even though [Connection 1] may not have been providing treatment and a copy of the authorization provided to [Connection 1] by the individual whose data was shared; and (ii) delete any data that it received from Carequality.** [Connection 1] should provide Particle with a written attestation that it has completed these activities and Particle shall provide a copy of the attestation to the Steering Committee.
- iii. Particle already provided to Epic a de-identified audit log of records obtained by [Connection 1] through Carequality. This list was in Exhibit H of Particle's June 17, 2024, submission. If Epic requests that PHI<sup>5</sup> be included in this audit log, then Particle will include relevant identifiers and deliver the identifiable data to Epic within 10 business days of receiving the request and confirm to the Steering Committee when it has delivered the identifiable audit log.

2. **[Connection 2]:**

- a. **Findings:** [Connection 2] and Particle each provided information to the Panel about [Connection 2]'s history with Carequality. Based on the information provided by [Connection 2] to the Panel, [Connection 2] confirmed that its queries were not for treatment purposes. Instead, [Connection 2] asserted that these requests [were] to provide patients (all of whom [Connection 2] received signed authorizations from) with their medical records [so that patients could discuss treatment options with their providers].<sup>6</sup>

On June 14, 2024, Particle notified the Panel that it had terminated its relationship with [Connection 2]. As a result, [Connection 2] is no longer a Carequality Connection. [Connection 2] informed the Panel that [Connection 2] has HIPAA-compliant authorizations for each request that it made through Carequality. In

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<sup>5</sup> Redaction Note: PHI means Protected Health Information.

<sup>6</sup> Redaction Note: Quote from Final Resolution was paraphrased to remove confidential information.

addition, [Connection 2] has confirmed in an email to Particle that it has deleted all patient health data obtained through Particle out of an abundance of caution. The Steering Committee adopts these findings.

b. **Resolution:**

- i. **[Connection 2] is not permitted to participate in Carequality for 12 months for any Permitted Purpose.** If [Connection 2] attempts to join Carequality after 12 months, it must secure approval from the Steering Committee prior to joining. This exclusion and subsequent approval requirement are applicable to [Connection 2] as well as any successor entity or any entity owned or operated by any of the owners of [Connection 2].
- ii. **Within 20 business days of the Steering Committee Resolution, Particle will demand that [Connection 2] provide to each health care provider from whom it received data (i) a notification that it received data through Carequality based on a query that asserted treatment even though [Connection 2] was not providing treatment; and (ii) a copy of the authorization provided to [Connection 2] by the individual whose data was shared.** [Connection 2] should provide Particle with a written attestation that it has completed these activities and Particle shall provide a copy of such attestation to the Steering Committee.
- iii. Particle already provided to Epic a de-identified audit log of records obtained by [Connection 2] through Carequality. This list was in Exhibit E of Particle's June 14, 2024, submission to the Steering Committee. If Epic requests that PHI be included in this audit log, then Particle will include relevant identifiers and deliver the identifiable data to Epic within 10 business days of receiving the request and confirm to the Steering Committee when it has delivered the identifiable audit log.

3. **[Connection 3]:**

- a. **Findings:** [Connection 3] onboarded to Carequality in [Date].<sup>7</sup> In [Dated], [description of corporate history of Connection 3]. [Connection 3] describes itself as a "[Connection 3's description from its corporate website]." According to information provided to the Panel by [Connection 3] (through Particle), [Connection 3] began working with [Organization A] in [Date] for [Organization A]'s [ ] Program. Beginning in [Date], Particle loaded OBO entries for [Connection 3] related to the [Organization A] [ ] Program and began making patient discovery requests to Epic from these OBO entries. On [Date], [Connection 3] learned that Epic was questioning its OBO entries. On [Date],

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<sup>7</sup> Redaction Note: Dates that can be used to identify a Connection have been redacted to maintain confidentiality.

[Connection 3] began reaching out to [ ] Program providers registered as OBO to request contact information for individuals Epic could talk to about the relationship with [Organization A] and [Connection 3]. On [Date], [Connection 3] paused implementation of its [ ] Program in relationship to Epic reaching out to question the [ ] Program treatment use case. The implementation of the [ ] Program remains paused to date.

- b. Epic’s primary allegation is that [Connection 3]’s use of Carequality to make queries in connection with the [Organization A] [ ] Program (“[ ] Queries”) is not treatment but may be payment or health care operations. Epic also alleges that (i) Particle published more than 1,000 entries duplicative of Epic and other Implementer’s sites in the Carequality Directory; (ii) Particle failed to remove OBO entries in timely manner after being notified of objections; and (iii) duplicative entries and likely additional invalid OBO relationships remain in the Directory today.
- c. The Panel engaged two privacy SMEs to provide guidance on whether [Connection 3]’s [ ] Queries were for treatment or another purpose. In providing guidance, the SMEs examined all relevant information provided by Epic and Particle and relevant information on the interpretation of HIPAA. While the SMEs acknowledged that HIPAA does not consider the activities of health plans to be “treatment” (see 65 Fed. Reg. 82627), the SMEs clarified that health plans *can* be business associates of health providers and make treatment related requests as part of their business associate services for health care providers.
- d. [Connection 3] (through Particle) provided a Template [ ] Program Provider BAA,<sup>8</sup> an example of the Template [ ] Program Provider BAA signed by a health care provider organization, and a Data Flow Map for the [ ] Program (see Attachment 13).
  - i. The Template [ ] Program Provider BAA is between a covered entity provider and [Organization A] as a business associate and enables [Organization A] to provide the [ ] services to the provider. The BAA is consistent with the requirements for Business Associates and BAAs under HIPAA although the Template does not contain a line for an effective date.
  - ii. Based on information provided in the Data Flow Map, no more than five authorized users of [Organization A] acting as a business associate of the [ ] Program Providers have limited, read-only access to the information collected by [Connection 3]. This access is for purposes of coordinating with the [ ] Providers to confirm whether they have, in treating their applicable patient, acted upon and/or verified any of the clinical diagnosis and condition alerts the [ ] Program Providers have received.

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<sup>8</sup> Redaction Note: BAA means Business Associate Agreement.

[Organization A] does not have the ability to download, extract or otherwise transfer the underlying clinical documentation collected by [Connection 3].

- iii. Taking the Data Flow Map and BAA together, the SMEs believe that [Connection 3], as a subcontractor/business associate of [Organization A], could be making [ ] Queries for treatment. The Steering Committee adopts this position.
- e. In the materials provided by [Connection 3] (through Particle), [Connection 3] acknowledges that in [3 month time period], [Connection 3] made [ ] Queries for each [ ] Program Provider's attributed active patient treatment roster to create baseline current diagnosis and condition listings for each patient. Based on the timeline provided by [Connection 3], these [ ] Queries appear to have occurred prior to [ ] Program Providers being given a meaningful opportunity to opt-out of the [Connection 3] [ ] Queries or to specify their preferences related to such [ ] Queries, which would have occurred later in the implementation phase. (See Attachment 13).
  - i. The SMEs acknowledge that there is commentary in the HIPAA Final Rule which says that "treatment refers to activities undertaken on behalf of a single patient, not a population" (65 FR 82462). The SMEs also acknowledge that it is very common for health care providers or their business associates to request information on a panel of patients to help inform the provider's treatment and often health care providers do not distinguish these activities as either treatment or health care operations. Likewise, the Steering Committee acknowledges that it is common for Carequality Implementers and health care provider Connections to request information on an individual basis for a panel of patients and utilize the treatment Permitted Purpose. While the line between treatment and health care operations for individual requests that are based on a panel or roster is unclear in light of technical advancements since HIPAA was first enacted, since the [ ] Queries based on the patient treatment roster occurred prior to the full implementation of the [ ] Program, the Steering Committee believes that they may not have been for treatment purposes.
- f. On a going-forward basis, provided the [ ] Program is implemented as represented in the information provided by [Connection 3], the Steering Committee believes that the [ ] Queries can be for treatment. Specifically, [Organization A] must have a BAA with each [ ] Program Provider on whose behalf [ ] Queries are made, the [ ] Program Provider must specify the triggers for the [ ] Queries (e.g. appointment), [ ] Program Providers must have the ability to opt-out of the [ ] Queries, and [Organization A] must not have access to the underlying clinical information collected by [Connection 3] except for the limited number of [Organization A] users who are providing services to the [ ] Program Providers as their business associate.

- g. With respect to Epic’s allegations about Particle’s duplicate entries into the Directory, Particle acknowledged that it had a technical issue. It worked expeditiously to rectify this issue and performed a root cause analysis to prevent a reoccurrence. (See Attachment 7).
- h. With respect to Epic’s allegation that Particle failed to remove OBO entries in a timely manner after being notified of objections, Particle asserted that it removed entries within at most five days (and within one day in the significant majority of cases) (See Attachment 2). Epic confirmed that as of June 12, 2024, all OBO entries previously objected to by Epic customers have been removed.
- i. With respect to Epic’s allegation that duplicative entries and likely additional invalid OBO relationships remain in the Directory today, Particle asserted that the previous duplicative entries were the result of a technical issue. The Steering Committee was not presented with specific evidence to substantiate that this continues to be an ongoing concern. However, with respect to the concern about the validity of OBO relationships, to confirm that only valid OBO relationships form the basis for a request, the Steering Committee has addressed this issue in its resolution below. (See Attachments 2 and 19).
- j. **Resolution:**
  - i. Given the concerns raised to date, each [Connection 3] OBO entry related to the [Organization A] [ ] Program must remain paused and cannot be used for [ ] Queries until Particle completes the following with respect to the respective OBO entry. Once the following is completed, [Connection 3] may resume [ ] Queries for treatment where appropriate.
    1. **Obtain Attestations from [Organization A] for BAAs with each [ ] Program Provider:** To ensure that [Organization A] has the appropriate authority to make [ ] Queries for treatment on behalf of providers, Particle must obtain from [Organization A] an attestation(s) that clearly and unequivocally states that [Organization A] has a valid, signed and dated business associate agreement that is substantially similar to the Template [ ] Program Provider BAA with each [ ] Program Provider on whose behalf [Connection 3] is making [ ] Queries. The attestation must list the [ ] Program Providers with whom [Organization A] has such a BAA and cannot include any caveats like “when required” or “if applicable.” Particle must retain this attestation(s) in the event that Carequality requests it as part of an audit.
    2. **Secure written confirmations of relationship between [Organization A] and health care providers on whose behalf [Connection 3] will be exchanging information:** To address the

concern about invalid OBO entries related to [Connection 3] and [Organization A], Particle must secure written confirmation of the relationship between [Organization A] and the health care provider on whose behalf [Connection 3] will be exchanging information. This written confirmation must be provided by an individual at the health care provider who has primary responsibility for the provider's privacy compliance (e.g. compliance officer or privacy officer) and the individual who serves as the main point of contact for the organization's relationship with its EHR<sup>9</sup> vendor. The written confirmation must also acknowledge [Organization A]'s relationship with [Connection 3]. Particle must provide a draft of the templated document to be signed by the health care provider organization confirming the relationship with [Organization A] for Carequality's review and approval. Particle must retain this documentation in the event that Carequality requests it as part of an audit.

- ii. **Deletion of Data:** With respect to the data received by [Connection 3] from the [ ] Queries it has made to date, [Connection 3] must delete such data unless it can (i) attest that [Organization A] had, at the time of the [ ] Queries, a signed BAA substantially similar to the Template [ ] Program Provider BAA with the [ ] Program Provider on whose behalf [Connection 3] made [ ] Queries; and (ii) secured the written confirmation required by 3(j)(i)(2), above, within twenty (20) business days following the Steering Committee Resolution. Particle is responsible for reporting to the Steering Committee that such deletions have occurred.

4. **Particle:**

a. **Findings:**

- i. With respect to Particle itself, the Steering Committee focused on whether Particle had (i) used a "masking gateway" to obstruct the source of queries; and (ii) met its obligations as a Carequality Implementer by conducting sufficient diligence on its Connections before approving and onboarding [Connection 1], [Connection 2], and [Connection 3] for the Treatment Permitted Purpose.
- ii. "Masking Gateway": Based on the information provided by a technical subject matter expert, the Steering Committee does not believe that Particle utilized a "masking gateway." Please see Section 5 for a more detailed summary of this issue.
- iii. Diligence: Despite the Steering Committee's findings regarding

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<sup>9</sup> Redaction Note: EHR means electronic health record.

[Connection 1] and [Connection 2], it does appear that Particle conducted diligence on each of these Connections although its diligence failed to reveal inaccurate information provided by each Connection. The Steering Committee also believes that Particle's current onboarding process, which was adopted by Particle in October 2023, appears to be relatively robust (see Attachment 11). Given that Particle experienced issues with multiple Connections despite having conducted diligence prior to onboarding, the Steering Committee finds that Particle should be subjected to additional oversight for six months to confirm that Particle is thoroughly following its process (see Resolution below). Specifically, with respect to each of the Connections in question, the Steering Committee found the following.

1. [Connection 1] was onboarded by Particle in [Date]. During the onboarding process, Particle asserted that it reviewed (i) a legal memorandum created by [Connection 1]'s counsel which described [Connection 1]'s business model and detailed [Connection 1]'s treatment use case; (ii) [Connection 1]'s responses to Particle's internal questionnaire; and (iii) [Connection 1]'s E1 submission. According to these materials, patients were utilizing [Connection 1]'s services to obtain a clinical review of their condition and health history by a licensed healthcare provider. These onboarding materials received by Particle are included as Attachment 6.
2. [Connection 2] was onboarded by Particle in [Date], prior to Particle's adoption of its current onboarding process. During the onboarding process, Particle asserted that it reviewed publicly available information, including [Connection 2]'s website, reviewed [Connection 2]'s completed Particle Health Use Case and Network Questionnaire, and it interviewed [Connection 2] at length on multiple occasions about its treatment use case. According to the Questionnaire, which was provided to the Steering Committee, [Connection 2] had BAAs with Covered Entities and would be providing services to small-to-mid size community practices that would use the information to personalize treatment plans for patients. According to an email provided to the Steering Committee, [Connection 2]'s CEO and Co-Founder confirmed to Particle in writing that [Connection 2] understood the Treatment Purpose of Use and would only query for the Treatment Purpose of Use. These onboarding materials received by Particle are included as Attachment 9.
3. [Connection 3] began working with [Organization A] in [Date]. Particle asserted that it had reviewed the use case including a letter from [Organization A] to [ ] Providers about [Connection 3]'s and [Organization A]'s use of Carequality to support the treatment provided by the [ ] Providers. In response to questions from

Carequality and Epic in [time period], Particle provided a letter from [Connection 3] and [Organization A] outlining their relationships with practices and their use and a [ ] Program Data Flow Map (which Data Flow Map was later updated in the supplemental materials included in Attachment 13). These materials are included as Attachment 12.

- b. **Resolution:** Given that Particle experienced issues with multiple Connections, the Steering Committee believes that implementation of a corrective action plan is appropriate. **As part of the corrective action plan, for six months following issuance of the Steering Committee Recommendation, Particle will be subject to the following:**
- i. **By the fifth business day of each month, Particle will submit to Carequality a list of all entries that Particle added to the Carequality Directory in the previous month.** The list will categorize each entry as a Candidate Implementer, Connection, initiator-only, initiator and responder, or On Behalf Of (OBO) entry. In addition, Particle will submit to Carequality the following statistics for the previous three months: (i) the number of patient discovery queries for each of its Candidate Implementers and Connections; (ii) the number of queries received by Particle and each of its Candidate Implementers and Connections from each other Implementer; (iii) the number of queries responded to by Particle and each of its Candidate Implementers and Connections for each other Implementer; and (iv) for how many patients documents are returned by each Candidate Implementer and Connection for each other Implementer.
    1. On a monthly basis, a subcommittee of the Steering Committee<sup>10</sup> will review the monthly reports submitted by Particle and identify 1-2 new Directory entries to review in further detail. For these new Directory entries, the subcommittee will request from Particle all documents and correspondence related to the new Directory entry's onboarding. The subcommittee will review the documentation and any other publicly available information about the new Directory entry to determine (i) whether Particle adequately followed its onboarding process; and (ii) whether the new Directory entry can appropriately assert Treatment as a Permitted Purpose.
    2. During the duration of the corrective action plan, the subcommittee will review at least 10 new Directory entries.

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<sup>10</sup> Given the Dispute Panel's knowledge of the issues presented in this Dispute, this subcommittee will be composed of the three Dispute Panel members plus two additional individuals identified by the Steering Committee. At least one of the additional members will be an Implementer that is a service provider (e.g. non-EHR).

3. The subcommittee may also ask Particle for additional information related to any anomalies it identifies in the new Directory reports or transaction volume reports (e.g. spike in volumes, high level of new OBO entries, incorrectly structured OBO entries) and Particle will cooperate in responding to such requests.
  4. In the event the subcommittee finds that Particle failed to adequately follow its onboarding process, entered a new Directory entry that cannot appropriately assert Treatment as a Permitted Purpose, or is otherwise not compliant with the Steering Committee Resolution, the subcommittee may recommend to the Steering Committee that (i) Particle's corrective action plan be extended on the same terms or (ii) Particle be deemed an Implementer not in good standing and prohibited from entering any new Directory entries until otherwise authorized by the Steering Committee.
- ii. **Particle will update its onboarding process to add a requirement that within two (2) weeks of activating a new Candidate Implementer/Connection, Particle must confirm that the Candidate Implementer/Connection is responding to requests in compliance with the reciprocity requirements as set forth in Carequality's Framework Policies, Connection Agreement, and Connection Terms.**
  - iii. **Understanding that Particle onboarded Candidate Implementers/Connections prior to adopting its new onboarding process, Particle will be given a grace period of two (2) weeks following the Steering Committee Resolution to review its Candidate Implementers/Connections and remove or inactivate any Directory entries for Candidate Implementers/Connections that may not be appropriately utilizing the Treatment Permitted Purpose.** Particle must report to Carequality any Directory entries that are removed or inactivated during this two week period, but will not be subject to further corrective action related to such entries. Following the end of such two-week period, Carequality will undertake a review of Particle's active Candidate Implementers/Connections to assess whether there is evidence that they are appropriately utilizing the Treatment Permitted Purpose.
  - iv. **Before listing any new OBO entries in the Directory, Particle must secure the written confirmation of the relationship from the organization on whose behalf the Particle Candidate Implementer/Connection will be exchanging information.**
    1. This written confirmation must be provided by an individual who has primary responsibility for the organization's privacy compliance (e.g. compliance officer or privacy officer) and the

individual who serves as the main point of contact for the organization's relationship with its EHR vendor. Particle must provide a draft of the templated document to be signed by the organization confirming the relationship with Particle's Candidate Implementer/Connection for Carequality's review and approval.

**v. If any Implementer or Carequality raises an objection to an existing Particle Candidate Implementer/Connection and provides objective evidence to Particle to substantiate its objection, Particle will immediately suspend such Candidate Implementer/Connection in the Directory.**

1. The Candidate Implementer/Connection must remain suspended until the objection can be overcome to the satisfaction of the Implementer that raised the objection or, at the election of Particle, the Candidate Implementer/Connection can be reviewed through the Issue Resolution Process.

vi. While the corrective action plan is in effect, if Carequality or the Steering Committee receives credible evidence that Particle is marketing its services in a manner that causes potential Candidate Implementers/Connections to provide inaccurate or incomplete information during the onboarding process or is encouraging potential Candidate Implementers/Connections to incorporate healthcare providers into a service offering in which the providers have a very limited role, then the Steering Committee may decide to (i) extend Particle's corrective action plan on the same terms, (ii) deem Particle an Implementer not in good standing and prohibit it from entering any new Directory entries, or (iii) immediately suspend Particle from engaging in exchange through Carequality.

vii. With the exception of any Candidate Implementers/Connections that Particle removes or inactivates during the two-week review period referenced above, while the corrective action plan is in effect, if Carequality or the Steering Committee receives credible evidence that another Particle Candidate Implementer/Connection provided incorrect information to Particle as part of its onboarding process, then the Steering Committee may decide to (i) extend Particle's corrective action plan period on the same terms, (ii) deem Particle an Implementer not in good standing and prohibit it from entering any new Directory entries, or (iii) immediately suspend Particle from engaging in exchange through Carequality.

**5. HCID and Gateway Findings**

Epic is arguing that Particle is "masking" the identity of its customers behind its gateway by putting its own Implementer-level homeCommunityId (HCID) in the SAML. To

support its position, Epic cited section 8.6 of the Carequality Directory Implementation Guide, which reads as follows:

The various identifier fields (other than HCID) populated by the ultimate initiator SHOULD use the most specific identifiers possible with the exception that returned HCID SHOULD specify the scope of the entity to which the patient’s data will be shared for the current disclosure. The “ultimate initiator” is the person or system that originated the message transaction. A non-normative example is a human clinician that queries an HIE via an EMR. All initiators MUST have an entry in the directory.

Particle argued that it was not masking its customers behind its gateway because it appropriately populated the relevant SAML attributes with its own identifier in the HCID as the Initiating Gateway, as well as the identifier for its specific initiating customer as the ultimate initiator in the organization-id (OrgID).

Historically Particle’s requests were being sent as:

```
<saml:Attribute Name="urn:nhin:names:saml:homeCommunityId">
  <saml:AttributeValue>urn:oid:Implementer-Level HCID</saml:AttributeValue>
</saml:Attribute>
<saml:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id">
  <saml:AttributeValue>urn:oid:Requesting CC OID</saml:AttributeValue>
</saml:Attribute>
```

Prior to the Dispute, at Epic’s request, Particle updated their SAML structure to instead populate the HCID to represent the query source:

```
<saml:Attribute Name="urn:nhin:names:saml:homeCommunityId">
  <saml:AttributeValue>urn:oid:Requesting CC OID</saml:AttributeValue>
</saml:Attribute>
```

The Panel engaged a technical SME to weigh in on the clarity in industry specifications pointed to by Carequality for use of these two identifiers in the SAML. The SME informed the Panel (and the Panel informed the Steering Committee) of the following:

Per the NHIN specifications (the relevant specifications referenced by the Carequality Query-Based Document Exchange Implementation Guide), the certificate used to establish the 2-way-TLS mutual gateway authentication should be the same as the certificate used to sign <timestamp> and <SAML> apexes of the SOAP message. These certificates can be different, and participants are advised to build their systems to accept different certificates for the 2-way-TLS purposes and the SOAP message signatures.

A Carequality Implementer sending a request for its Connection could choose to create and sign the SAML assertion and secure mTLS with the same Carequality-issued certificate or could alternately pass through a SAML assertion signed by the

Connection, but only if the Connection has its own certificate issued by Carequality.

NHIN Authorization Framework Section 3.2.2.3 specifies that organization-id contains an identifier for the organization whose name is listed in the free-text Organization field. An argument could be made that versions of specifications pointed to by Carequality are slightly vague about populating that organization-id.

NHIN Authorization Framework Section 3.2.2.4 ties HCID to the identifier of the Health Information Organizations (HIOs) who act as Initiating Gateways on the Nationwide Health Information Network (NHIN). As Carequality points to the NHIN Authorization Framework, HIOs are generally understood to be Implementers. However, in some cases a Connection may be the Initiating Gateway itself.

The most common deployment of these two identifiers would be the sending Implementer Gateway as HCID with the more specific edge system as OrgID.

The latest NHIN spec (not pointed to by Carequality) adds clarity that HCID is the last of any intermediaries to send the message before it reaches the Hub. In Carequality (which does not have a central Hub model) that would be the Implementer or Connection who establishes the mTLS connection with their Carequality certificate to another Implementer or Connection Responding Gateway.

**Summary:** Based on current specifications, organization-Id should represent the most granular organization who initiated the request; HCID should represent the organization whose Carequality certificate is used to open the mTLS and send the SOAP message. Based on Particle's architecture, this means that the HCID should always represent Particle. The Steering Committee adopts this position.

6. **Epic:**

- a. **Findings:** With respect to Epic, the Steering Committee focused on whether Epic (i) failed to comply with the Carequality Framework requirements by failing to load into its local directory all Particle Directory entries for treatment; and (ii) discriminated against Particle with respect to the processing of Directory entries and the resulting exchange of information (or lack thereof for entries that Epic did not load into its directory).
- b. Epic's decision to not load all Particle Directory entries into its local directory is the result of Epic's application of its "Policies for Reviewing New and Updated Carequality Directory Entries" (the "Phonebook Policy") (See Attachment 14). While Epic did not label it as an "Applicant Business Rule," the Steering Committee believes that the Phonebook Policy is likely akin to an Applicant Business Rule and therefore would be generally permissible under the Carequality

Connected Agreement. That said, the Steering Committee does acknowledge that the Phonebook Policy lacks, and Epic did not provide upon request, clear and objective criteria to be used by Epic and the Care Everywhere Governing Council to determine whether a Directory entry is performing treatment. If Epic adopts clear, objective criteria to determine whether a Directory entry is performing treatment and it applies those criteria consistently across all Directory entries, then Epic's compliance with its Phonebook Policy and resulting determination to not load into its local directory all Particle Directory entries for treatment would not violate the CCA.

- c. Epic provided data on the number of new Directory entries it reviewed between January 1, 2024 – July 18, 2024. According to the data provided, Epic reviewed 6,450 new Directory entries. It processed 6,199 of those Directory entries as treatment and added them to Epic's local directory. It has not loaded 251 of those Directory entries for various reasons. Of the 251 Directory entries that have not been loaded, 23 are Particle entries. Of the 11 that Epic found not to be treatment, 3 are Particle Health Candidate Implementers/Connections. Based on these statistics, the Steering Committee does not believe that Epic is treating Particle differently than it is treating other Implementers.
- d. The Steering Committee notes that Epic has decided to not load 125 entries since January 1, 2024, and to the Steering Committee's knowledge is not in active discussions with the respective Implementers. It is unclear whether these Implementers are aware that Epic has not loaded these entries.
- e. **Resolution:**
  - i. **Within one (1) month of the Steering Committee Resolution, Epic will update its Phonebook Policy to include clear, objective criteria to be used by Epic and the Care Everywhere Governing Council to determine whether a Directory entry is performing treatment.**
    1. Epic will provide a copy of the updated Phonebook Policy to the Steering Committee.
    2. For transparency, Epic will make a copy of the Phonebook Policy available to any Implementer that requests a copy.
  - ii. **For a period of six months following the Steering Committee Resolution, within two (2) weeks of Particle adding any new Directory entries to the Carequality Directory, Epic will process the Directory entry in accordance with its Phonebook Policy.**
    1. In the event that Epic does not load the Directory entry to its local directory within that 2-week period, Epic will provide to Particle and Carequality a written notification that such entry has not been

loaded and will specify the objective criteria from the Phonebook Policy that is in question or that the entry failed to meet.

2. In the event that Particle provides evidence that the Directory entry meets the criteria, Epic will load the entry into its local directory. In the event that Epic and Particle disagree on the sufficiency of the evidence, the Steering Committee or subcommittee thereof shall review and provide guidance.
- iii. **For a period of six months following the Steering Committee Resolution, by the fifth business day of each month, Epic will provide to Carequality a report showing all new Directory entries added to the Carequality Directory during the previous month, the associated Implementer, and how those entries were dispositioned by Epic (e.g. processed as treatment and added to Epic's local directory, processed as non- treatment, unable to confirm treatment, active review and discussion with implementer).**
  1. For any entry that is not processed as treatment, the report must indicate the criteria from the Phonebook Policy that is in question or that the entry failed to meet.
- iv. Based on the recent policy direction from the Steering Committee, the Steering Committee understands that if an Implementer's or Connection's consistent application of its Business Rules, as defined in the Carequality Connected Agreement and Connection Terms, would prohibit the Implementer or Connection from exchanging with a specific Connection, the Implementer's or Connection's failure to engage in such exchange will not violate the Carequality Framework agreements or policies. **In the event the Steering Committee provides further guidance on the use of Applicant Business Rules, Epic must act in accordance with such guidance.**
- v. **Epic will refrain from instructing Implementers to change their SAML assertions to include the Connection's identifier in the HCID instead of or in addition to the OrgID.**

## **7. Public Statement**

- a. The Steering Committee will discuss notification to all Implementers of the Steering Committee Resolution once it is accepted by the parties and will discuss issuing a public statement regarding the resolution of the Dispute.

## ***V. RESOLUTIONS FOR IMPLEMENTER COMMUNITY AT LARGE***

1. While the Steering Committee considers further guidance regarding use of Applicant Business Rules, in the interim, for transparency, the Steering Committee will direct each

Implementer to make available a copy of any Applicant Business Rules or similar policies to any Implementer that requests a copy.

2. The Steering Committee will continue to consider further guidance surrounding Applicant Business Rules including requiring each Implementer that has adopted Applicant Business Rules to: 1) notify each other Implementer if it will not be exchanging information with an Implementer's Connection or will not be loading a new Directory entry into its local directory because it does not meet the Implementer's Applicant Business Rules and, 2) provide the criteria from any applicable Applicant Business Rules that the Connection or entry failed to meet. If the Implementer provides evidence that the Connection or entry meets such criteria, that Implementer will load the entry into its local directory.
3. To better align with TEFCA and promote trust in Carequality, the Steering Committee will consider that before listing any new OBO entries in the Directory, each Implementer must secure the written confirmation of the relationship from the organization on whose behalf the Implementer's Candidate Implementer/Connection will be exchanging information. This written confirmation must be provided by an individual who has primary responsibility for the organization's privacy compliance (e.g. compliance officer or privacy officer) and the individual who serves as the main point of contact for the organization's relationship with its EHR vendor.

## APPENDIX 1

### Key Materials that Informed the Steering Committee’s Resolution

Attachment No.	Name of Document	Description
1	Epic Pre-Dispute Statement	Epic Dispute summary submission dated April 24, 2024
2	Particle Counter Statement	Particle’s statement in response to Epic’s Pre-Dispute Statement, received May 3, 2024
3	Particle Dispute Statement	Particle Dispute submission, received May 3, 2024
4	Particle Health Dispute – Epic Counter Statement	Epic’s statement in response to Particle’s Dispute submission, dated May 24, 2024
5	2024.06.17 Letter to Carequality Legal Counsel	Particle Letter to Carequality legal counsel providing Particle’s responses to the Dispute Panel’s initial document requests and questions, dated June 17, 2024
6	Onboarding Materials for [Connection 1] Reviewed by Particle	[Connection 1] E-1 Submission
Exhibit D to Attachment 5: copy of onboarding forms that contain [Connection 1]’s responses to Particle’s Customer Onboarding Questions		
Exhibit E and F to Attachment 5: Two legal memoranda presented by [Connection 1] to demonstrate treatment use case		
7	Email, RE: Epic v. Particle Dispute – Particle Follow-Up to Q&A	Email from Particle’s legal counsel to the Panel, notifying Panel of [Connection 1] termination, dated June 27, 2024. Also contains discussion directory-related issues, bi-directionality, and OBO entries.

<b>8</b>	[Connection 2] Ltr to Carequality re Epic and Particle Health Dispute	Letter from [Connection 2] CEO to Carequality Steering Committee and Carequality, dated May 22, 2024
<b>9</b>	Confidential Particle Response Letter Re [Connection 2]	Letter from Particle to Panel in response to the letter from [Connection 2] (Attachment 8), received June 12, 2024
<b>10</b>	Confidential Particle Health – [Connection 2] Email	Email from Particle legal counsel providing Attachment 9 to the Steering Committee, dated June 14, 2024
<b>11</b>	Exhibit B – Particle Customer Onboarding Process	Exhibit B to Attachment 7 provides a chart contained in Particle’s onboarding policy.
<b>12</b>	Background Materials Considered Specific to Claims Surrounding [Connection 3]	Exhibit I to Attachment 5: Template contract for [ ] Program provided by [Connection 3]
		Exhibit J to Attachment 5: Attestation from [Provider Organization] about its participation in the [ ] Program
		Exhibits K and L to Attachment 5: Initial letter and follow-up letter set to providers about the [ ] Program
		[Organization A] Attestation Regarding Arrangement with Providers Related to the [ ] Program and Related Programs
<b>13</b>	[Connection 3] Responses to Panel Follow-Up Questions	[Connection 3] Responses to Carequality Panel Follow-Up Questions, dated August 6, 2024
		Example Provider Business Associate Agreement - Exhibit 1-A
		[ ] Program Data Flow Map - Exhibit 1-B
<b>14</b>	Carequality Phonebook Support Policy	Epic’s Onboarding Policy, revised as of February 28, 2024, implemented in early 2021.

<b>15</b>	Epic June 20 Panel Presentation	Slides presented by Epic to the Dispute Panel during June 20 Panel Meeting
<b>16</b>	Particle Dispute Presentation	Slides presented by Particle to the Dispute Panel during June 20 Panel Meeting
<b>17</b>	Epic July 23 Panel Presentation	Slides presented by Epic to the Dispute Panel during July 23 Panel Meeting
<b>18</b>	Description of Masking Claim	Appendix C: How Particle Masked Its Customers' Identities
<b>19</b>	Particle Bi-Directionality and Directory Management Descriptions	Exhibit C to Attachment 7 describes Particle's directory management process
		Exhibit E to Attachment 7 – describes Particle's Bi-Directionality Implementation Process
		Exhibit F to Attachment 7 – C-CDA Creation Guide for Bi-Directionality