RESOLUTION AGREEMENT

I. Recitals

1. Parties.

The Parties to this Resolution Agreement ("Agreement") are:

A. The United States Department of Health and Human Services ("HHS"), Office for Civil Rights ("OCR"), which enforces the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A and E of Part 164, the "Privacy Rule"), the Federal standards that govern the security of electronic individually identifiable health information (45 C.F.R. Part 160 and Subparts A and C of Part 164, the "Security Rule"), and the Federal standards for notification in the case of breach of unsecured protected health information (45 C.F.R. Part 160 and Subparts A and D of 45 C.F.R. Part 164, the "Breach Notification Rule"). HHS has the authority to conduct compliance reviews and investigations of complaints alleging violations of the Privacy, Security, and Breach Notification Rules (the "HIPAA Rules") by covered entities and business associates, and covered entities and business associates must cooperate with HHS compliance reviews and investigations. *See* 45 C.F.R. §§ 160.306(c), 160.308, and 160.310(b).

B. Dr. Linda Shen d/b/a/ Shen Smiles, P.C., ("Shen Smiles") meets the definition of "covered entity" under 45 C.F.R. § 160.103 and therefore is required to comply with the HIPAA Rules.

C. HHS and Shen Smiles shall together be referred to herein as the "Parties."

2. Factual Background and Covered Conduct.

Shen Smiles is a solo dental practice with Dr. Linda Shen as the sole owner. It is legally organized as a professional corporation. Shen Smiles maintains an office in Drums, Pennsylvania.

Shen Smiles is a health care provider that transmits health information in electronic form in connection with transactions for which the U.S Department of Health and Human Services has adopted standards. Shen Smiles accepts multiple health care insurance plans, including Pennsylvania Medicaid, to which it submits claims electronically. Shen Smiles creates, maintains, receives, and transmits protected health information (PHI) related to patients for whom Shen Smiles provides dental care. Shen Smiles is a "covered entity" within the meaning of 45 C.F.R. § 160.103, and, as such, is required to comply with the requirements of the Privacy, Security, and Breach Notification Rules. Because Shen Smiles is a covered entity under HIPAA, it is required to comply with the HIPAA Privacy Rule, which includes reasonably safeguarding PHI from any intentional or unintentional use or disclosure, implementing HIPAA compliant policies and procedures, and maintaining those policies and procedures provided for in 45 C.F.R. § 164.530(i) in written or electronic form.

On April 21, 2020, OCR received a complaint from the attorney of a former patient ("Affected Party") against Shen Smiles. The complaint alleged that Shen Smiles did not provide Affected Party with access to Affected Party's PHI following multiple access requests made by

Affected Party. On May 20, 2020, OCR notified Shen Smiles in writing of the complaint and its intent to investigate the matter and issued data requests.

OCR learned during its investigation that Shen Smiles's patient records were not properly maintained. OCR's investigation also determined that Shen Smiles did not provide its employees with formal HIPAA Privacy Rule training.

OCR's investigation indicated the following potential violations likely occurred ("Covered Conduct"):

A. Shen Smiles failed to produce evidence that it had implemented policies and procedures with respect to PHI that are designed to comply with both the Privacy Rule and the Breach Notification Rule, as required by 45 C.F.R. § 164.530(i).

B. Shen Smiles failed to produce evidence that it had reasonably safeguarded PHI from any intentional or unintentional use or disclosure of PHI that would violate the requirements of the Privacy Rule, as required by 45 C.F.R. § 164.530(c)(2)(i).

OCR notified Shen Smiles of the results of its investigation by email on November 27, 2023, and by U.S. Mail on November 28, 2023.

OCR sent a Letter of Opportunity (LOO) to Shen Smiles on January 3, 2024. The LOO informed Shen Smiles that OCR's investigation indicated that Shen Smiles failed to comply with the Privacy Rule, specifically 45 C.F.R. § 164.530(i)(1) and 164.530(c)(2)(i). The LOO stated that pursuant to 45 C.F.R. § 160.312(a)(3), OCR was informing Shen Smiles of the preliminary indications of noncompliance and providing Shen Smiles with an opportunity to submit written evidence of mitigating factors under 45 C.F.R. § 160.408 or affirmative defenses under 45 C.F.R. § 160.410 for OCR's consideration in making a determination of a civil monetary penalty ("CMP") pursuant to 45 C.F.R. § 160.404. The letter stated that Shen Smiles could also submit written evidence to support a waiver of a CMP for the indicated areas of noncompliance pursuant to 45 C.F.R. § 160.412. Shen Smiles responded to the LOO by letter dated February 6, 2024.

A Noticed of Proposed Determination (NPD) was sent on July 31, 2024 informing Shen Smiles that OCR was proposing to impose a CMP of $140,000 for potential violations of 45 C.F.R. § 164.530(i)(1) for Shen Smile's failure to implement policies and procedures with respect to PHI that are designed to comply with both the Privacy Rule and the Breach Notification Rule requirements, and 45 C.F.R. § 164.530(c)(2)(i) for failure to reasonably safeguard PHI from any intentional or unintentional improper use or disclosure at the reasonable cause penalty tier. OCR also determined that the information and arguments submitted by Shen Smiles in response to the LOO did not support an affirmative defense or a waiver of the CMP.

On November 8, 2024, Shen Smiles filed an appeal with the Civil Remedies Division, Departmental Appeals Board, to request a hearing regarding OCR's findings that Shen Smiles violated the Privacy Rule and the proposed penalty of $140,000.

3. No Admission. This Agreement is not an admission of liability by Shen Smiles.

4. No Concession. This Agreement is not a concession by HHS that Shen Smiles is not in violation of the HIPAA Rules and not liable for civil monetary penalties.

5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve HHS Transaction Number 20-380382 and the related appeal filed in the Departmental Appeals Board, Docket No. C-25-108, arising from any potential violations of the HIPAA Rules related to the Covered Conduct specified in paragraph 2 of this Agreement occurring on or before November 27, 2023. In consideration of the Parties' interest in avoiding the uncertainty, burden, and expense of continued proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

II. Terms and Conditions

6. Payment. HHS has agreed to accept, and Shen Smiles has agreed to pay HHS, the amount of $140,000 ("Resolution Amount"). Shen Smiles agrees to pay the Resolution Amount in one-lump sum on the Effective Date of this Agreement as defined in paragraph Il.14 pursuant to written instructions to be provided by HHS.

7. Release by HHS. In consideration of and conditioned upon Shen Smiles's performance of its obligations under this Agreement, HHS releases Shen Smiles from any actions it may have against Shen Smiles under the HIPAA Rules arising out of or related to the Covered Conduct identified in paragraph I.2 of this Agreement occurring on or before November 27, 2023. HHS does not release Shen Smiles, nor waive any rights, obligations, or causes of action other than those arising out of or related to the Covered Conduct and referred to in this paragraph. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.

8. Agreement by Released Parties. Shen Smiles shall not contest the validity of its obligation to pay, nor the amount of, the Resolution Amount or any other obligations agreed to under this Agreement. Shen Smiles waives all procedural rights granted under section 1128A of the Social Security Act (42 U.S.C. § 1320a- 7a) and 45 C.F.R. Part 160 Subpart E, and HHS claims collection regulations at 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.

9. Binding on Successors. This Agreement is binding on Shen Smiles and its successors, heirs, transferees, and assigns.

10. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

11. No Additional Releases. This Agreement is intended to be for the benefit of the Parties only and by this instrument the Parties do not release any claims against or by any other person or entity.

12. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

13. Execution of Agreement and Effective Date. The Agreement shall become effective *(i.e.*, final and binding) upon the date of signing of this Agreement by the last signatory

(Effective Date).

14. Disclosure. HHS places no restriction on the publication of the Agreement.

15. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

16. Authorizations. The individual(s) signing this Agreement on behalf of Shen Smiles represents and warrants that they are authorized to execute this Agreement and bind Shen Smiles, as set forth in paragraph I.1.b. The individual(s) signing this Agreement on behalf of HHS represent and warrant that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

17.

For Dr. Linda L. Shen, DDS d/b/a/ Shen Smiles

//s// 8/10/26

Andrew J. Katsock, III — Date
Counsel for Dr. Linda L. Shen, DDS d/b/a/ Shen Smiles
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//s// 8/10/26

Linda Shen, DDS — Date
Shen Smiles, PC
10 Rittenhouse Place Drums, PA 18222

For U.S. Department of Health and Human Services

//s// 8/11/26

Marisa M Smith, Ph.D. — Date
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