

RESOLUTION AGREEMENT

I. Recitals

1. Parties. The Parties to this Resolution Agreement (“Agreement”) are:

A. The United States Department of Health and Human Services, Office for Civil Rights (“HHS”), 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. Cornell Prescription Pharmacy (“CPP”), which is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. CPP is a Colorado for-profit, S-Corporation, single location, compounding pharmacy.

HHS and CPP shall together be referred to herein as the “Parties.”

2. Factual Background and Covered Conduct.

On January 13, 2012, the HHS Office for Civil Rights (OCR) initiated a compliance review and investigation of CPP following receipt of a media report dated January 11, 2012. Specifically, OCR received a report from 9 News, the Denver National Broadcast Company news affiliate, that protected health information (PHI) maintained by CPP was disposed of in a dumpster that was accessible to the public. On February 27, 2012, OCR notified CPP of its investigation regarding its compliance with the Privacy Rule. OCR’s investigation indicated that the following conduct occurred (“Covered Conduct”):

- A. CPP failed to reasonably safeguard PHI. *See* 45 C.F.R. § 164.530(c)(1).
- B. CPP failed to implement written policies and procedures to comply with the Privacy Rule. *See* 45 C.F.R. § 164.530(i)(1).
- C. From the compliance date of the Privacy Rule to the present, CPP did not provide, and did not document, training on its Privacy Rule policies and procedures as

necessary and appropriate for the members of its workforce. *See* 45 C.F.R. § 164.530(b)(1).

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

4. No Concession. This Agreement is not a concession by HHS that CPP is not in violation of the Privacy Rule and that CPP is not liable for civil money penalties.

5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve HHS Transaction Number: 12-137644 and any violations of the HIPAA Privacy, Security, and Breach Notification Rules related to the Covered Conduct specified in Paragraph I.2 of this Agreement. In consideration of the Parties' interest in avoiding uncertainty, burden and expense of further investigation and formal 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 CPP has agreed to pay HHS, the amount of \$125,000 ("Resolution Amount"). CPP agrees to pay the Resolution Amount on the Effective Date of this Agreement as defined in Paragraph II.14 by automated clearinghouse transaction pursuant to written instructions to be provided by HHS.

7. Corrective Action Plan. CPP has entered into and agrees to comply with the Corrective Action Plan (CAP), attached as Appendix A, which is incorporated into this Agreement by reference. If CPP breaches the CAP, and fails to cure the breach as set forth in the CAP, then CPP will be in breach of this Agreement and HHS will not be subject to the release set forth in Paragraph II.8 of this Agreement.

8. Release by HHS. In consideration and conditioned upon CPP's performance of its obligations under this Agreement, HHS releases CPP from any actions it may have against CPP under the Privacy, Security, and Breach Notification Rules arising out of or related to the Covered Conduct specified in Paragraph I.2 of this Agreement. HHS does not release CPP from, 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.

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

10. Binding on Successors. This Agreement is binding on CPP and its successors, heirs, transferees, and assigns.

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

12. 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.

13. 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.

14. Execution of Agreement and Effective Date. This Agreement shall become effective (*i.e.*, final and binding) upon the date of signing this Agreement and the CAP by the last signatory (“Effective Date”).

15. Tolling of Statute of Limitations. Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a civil money penalty (“CMP”) must be imposed within six (6) years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this Agreement, CPP agrees that the time between the Effective Date of this Agreement and the date this Agreement may be terminated by reason of CPP’s breach, plus one year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the violations which are the subject of this Agreement. CPP waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct specified in Paragraph I.2 that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Agreement.

16. Disclosure. HHS places no restriction on the publication of the Agreement. In addition, HHS may be required to disclose this Agreement and related material to any person upon request consistent with the applicable provisions of the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and its implementing regulations, 45 C.F.R. 5.

17. 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.

18. Authorizations. The individual(s) signing this Agreement on behalf of CPP represent and warrant that they are authorized by CPP to execute this Agreement. 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.

For Cornell Prescription Pharmacy

Tony Jones, Owner

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CORNELL PRESCRIPTION PHARMACY

I. Preamble

Cornell Prescription Pharmacy (hereinafter referred to as CPP) hereby enters into this Corrective Action Plan (CAP) with the United States Department of Health and Human Services, Office for Civil Rights (HHS). Contemporaneously with this CAP, CPP is entering into a Resolution Agreement (Agreement) with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. CPP enters into this CAP as part of the consideration for the release set forth in Paragraph II.8 of the Agreement.

II. Contact Persons and Submissions

A. Contact Persons

CPP has identified the following individual as its authorized representative and contact person regarding the implementation of this CAP and for the receipt and submission of notifications and reports:

Mr. Tony Jones, Owner
Cornell Prescription Pharmacy
2190 East 18th Avenue
Denver, Colorado 80206

HHS has identified the following individual as its contact person to whom CPP is to report information regarding implementation of this CAP:

Ms. Andrea Oliver, Regional Manager
Office for Civil Rights, Region VIII
Department of Health and Human Services
999 18th Street, South Terrace, Suite 417
Denver, Colorado 80202

CPP and HHS agree to promptly notify each other of any changes in the contact persons or the other information provided above.

Proof of Submissions. Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

III. Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with Paragraph II.14 of the Agreement (“Effective Date”). The period for compliance (“Compliance Term”) with the obligations assumed by CPP under this CAP shall begin on the Effective Date of this CAP and end two (2) years from the Effective Date unless HHS has notified CPP under section VIII hereof of its determination that CPP has breached this CAP. In the event of such a notification by HHS under section VIII hereof, the Compliance Term shall not end until HHS notifies CPP that it has determined that the breach has been cured. However, after the Compliance Term ends, CPP shall still be obligated to submit the final Annual Report as required by section VI and comply with the document retention requirement in section VII.

IV. Time

In computing any period of time prescribed or allowed by this CAP, all days referred to shall be calendar days. The day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day that is not one of the aforementioned days.

V. Corrective Action Obligations

CPP agrees to the following:

A. Policies and Procedures.

1. CPP shall develop, maintain, and revise, as necessary, written policies and procedures to comply with 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). CPP’s policies and procedures shall include, but not be limited to, the minimum content set forth in section V.C below.

2. CPP shall provide such policies and procedures, consistent with Paragraph V.A.1 above, to HHS within 30 days of the Effective Date for review and approval. Upon receiving any recommended changes to such policies and procedures from HHS, CPP shall have 30 days to revise such policies and procedures accordingly and provide the revised policies and procedures to HHS for review and approval.

3. CPP shall adopt and begin implementation of such policies and procedures within 30 days of receipt of HHS’ final approval.

B. Distribution and Updating of Policies and Procedures.

1. CPP shall distribute the policies and procedures identified in section V.A to all members of its workforce within 30 days of HHS approval of such policies and procedures and to new members of the workforce within 30 days of their beginning of service.

2. CPP shall require, at the time of distribution of such policies and procedures, a signed written or electronic initial compliance certification from each member of the workforce, stating that the workforce member has read, understands, and shall abide by such policies and procedures.

3. CPP shall assess and update and revise, as necessary, the policies and procedures at least annually. CPP shall provide such revised policies and procedures to HHS for review and approval. Upon receiving any recommended changes to such policies and procedures from HHS, CPP shall have 30 days to revise such policies and procedures accordingly and provide the revised policies and procedures to HHS for review and approval. Within 30 days of the effective date of any approved, substantive revisions, CPP shall distribute such revised policies and procedures to all members of its workforce, and to new members as required by Section V.B.1, and shall require new compliance certifications.

4. CPP shall not involve any member of its workforce in the use or disclosure, including disposal, of PHI if that workforce member has not signed or provided the written or electronic certification required by Paragraphs V.B.2 and V.B.3 of this section.

C. Minimum Content of the Policies and Procedures.

The Policies and Procedures shall include, but not be limited to:

1. Administrative and physical safeguards for the disposal of all non-electronic PHI that appropriately and reasonably safeguard such PHI from any use or disclosure in violation of the Privacy Rule and that limit incidental uses and disclosures, including, but not limited to, providing that paper PHI intended for disposal shall be shredded, burned, pulped, or pulverized so that the PHI is rendered essentially unreadable, indecipherable, and otherwise cannot be reconstructed.

2. Measures that address the following Privacy Rule provisions:

a. Uses and disclosures of PHI – 45 C.F.R. § 164.502(a)

b. Safeguards – 45 C.F.R. § 164.530(c)(1)

c. Training – 45 C.F.R. § 164.530(b)(1)

d. Internal Reporting Procedures - CPP shall require all members of its workforce to report to the designated Privacy Officer at the earliest possible time, any violation of the Policies and Procedures of which she or he is aware.

3. Measures providing that upon receiving information that a member of its workforce may have violated these policies and procedures, CPP shall promptly investigate and address the violation in an appropriate and timely manner.

4. Application of appropriate sanctions (which may include re-training or other instructive corrective action, depending on the circumstances) against members of CPP's workforce, including supervisors and managers, who fail to comply with the CPP Policies and Procedures.

D. Training.

1. All members of CPP's workforce shall receive training on CPP's policies and procedures to comply with the Privacy Rule within 30 days of the implementation of the policies and procedures, or within 30 days of when they become a member of the workforce of CPP.

2. At a minimum, training shall cover all of the topics that are necessary and appropriate for each member of the workforce to carry out that workforce member's function within CPP.

3. Each workforce member shall certify, in writing or in electronic form, that she or he has received and understands the required training. The training certification shall specify the date on which training was received. All course materials shall be retained in compliance with section VII below.

4. CPP shall review the training annually, and, where appropriate, update the training to reflect changes in Federal law or HHS guidance, any issues discovered during internal or external audits or reviews, and any other relevant developments.

5. CPP shall not involve any member of its workforce in the use or disclosure, including disposal, of PHI if that workforce member has not provided written or electronic training certification required by Paragraph V.D.3 of this section.

E. Reportable Events.

1. During the Compliance Term, CPP shall, upon receiving information that a workforce member may have failed to comply with its Policies and Procedures or otherwise that there may have been a violation of the HIPAA Rules, promptly investigate the matter. If CPP determines, after review and investigation, that a member of its workforce has failed to comply with its Policies and Procedures or that there has otherwise been a violation of the HIPAA Rules, CPP shall notify HHS in writing within thirty (30) days. Such violations shall be known as "Reportable Events." The report to HHS shall include the following:

a. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of CPP's Policies and Procedures or HIPAA Rules implicated; and

b. A description of the actions taken and any further steps CPP plans to take to address the matter, to mitigate any harm, and to prevent it from recurring, including the application of appropriate sanctions against workforce members who failed to comply with its Policies and Procedures or otherwise violated the HIPAA Rules.

2. If no Reportable Events occur within the Compliance Term, CPP shall so inform OCR in its Annual Reports.

VI. Implementation Report and Annual Reports

A. Implementation Report. Within 60 days after receiving HHS' approval of the Policies and Procedures required by section V.A., CPP shall submit a written report to HHS summarizing the status of its implementation of the obligations of this CAP. The Implementation Report shall include:

1. An attestation signed by CPP's owner attesting that the Policies and Procedures required by section V.A.: (a) have been adopted; (b) are being implemented; (c) have been distributed to all members of the workforce, in accordance with Paragraphs V.B; and (d) that CPP obtained all the compliance certifications in accordance with Paragraph V.B.2 and V.B.3;

2. A copy of all training materials used for the training required by this CAP, a description of the training, including a summary of the topics covered, the length of the session(s), and a schedule of when the training(s) were held;

3. An attestation signed by the owner of CPP attesting that all members of the workforce have completed the initial training required by this CAP and have executed the training certifications required by section V.E.3; and

4. An attestation signed by CPP's owner stating that he has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information contained therein is accurate, truthful, and complete.

B. Annual Reports. The one-year period beginning on the Effective Date and each subsequent one-year period during the course of the period of compliance obligations shall be referred to as the Reporting Periods. CPP shall submit to HHS Annual Reports with respect to the status of and findings regarding CPP's compliance with this CAP for each of the annual Reporting Periods. CPP shall submit such Annual Reports to HHS no later than 45 days after the end of each corresponding Reporting Period. The Annual Report shall include:

1. A schedule, topic outline, and copies of the training materials for the training programs attended or provided in accordance with this CAP during the Reporting Period that is the subject of the report.

2. An attestation signed by CPP's owner or designated Privacy Officer attesting that it is obtaining and maintaining written or electronic training certifications from all workforce

members and that attest that such persons received training pursuant to the requirements set forth in this CAP.

3. A summary of Reportable Events, as defined in section V.D.1, identified during the Reporting Period and the status of any corrective or preventive action relating to all such Reportable Events.

4. An attestation signed by CPP's owner or designated Privacy Officer attesting that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate, truthful, and complete.

VII. Document Retention

CPP shall maintain for inspection and copying, and shall provide to OCR upon request, all documents and records relating to compliance with this CAP for six (6) years from the Effective Date.

VIII. Breach Provisions

CPP is expected to fully and timely comply with all provisions of this CAP.

A. Timely Written Requests for Extensions. CPP may, in advance of any due date set forth in this CAP, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CAP. A "timely written request" is defined as a request in writing received by HHS at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

B. Notice of Breach and Intent to Impose CMP. The Parties agree that a breach of this CAP by CPP constitutes a breach of the Resolution Agreement. Upon a determination by HHS that CPP has breached this CAP, HHS may notify CPP of: (a) CPP's breach; and (b) HHS' intent to impose a civil money penalty (CMP) pursuant to 45 C.F.R. Part 160 for the Covered Conduct set forth in Paragraph I.2 of the Resolution Agreement and any other conduct that constitutes a violation of the HIPAA Rules (this notification is hereinafter referred to as the "Notice of Breach and Intent to Impose CMP").

C. CPP's Response. CPP shall have 30 days from the date of receipt of the Notice of Breach and Intent to Impose CMP to demonstrate to HHS' satisfaction that:

1. CPP is in compliance with the obligations of the CAP cited by HHS as being the basis for the breach;

2. The alleged breach has been cured; or

3. The alleged breach cannot be cured within the 30-day period, but that: (i) CPP has begun to take action to cure the breach; (ii) CPP is pursuing such action with due diligence; and (iii) CPP has provided to HHS a reasonable timetable for curing the breach.

