

# Office for Civil Rights Resolution Agreement

## Sample Corrective Action Plan (“CAP”) Implementation Outline Based on New England Dermatology and Laser Center

### Within 60 days of Effective Date

#### ➤ Policies and Procedures

- ✓ Develop, maintain, and revise all HIPAA Privacy Rule Policies and Procedures (“P&Ps”) and submit to HHS for review and approval within 60 days
  - \*Need to validate with HHS that your list of P&Ps is complete and accurate*
    - If HHS has recommended changes = 30 days to revise and resubmit to HHS for approval
    - After HHS approval, 30 days to implement
  - \*Need to ensure an accurate and efficient process for review, approval, and revision of all HIPAA Privacy P&Ps*
- ✓ Specifically address HIPAA Privacy Rule P&Ps relative to:
  - §164.530(c) Administrative Requirements
  - §164.502(a) Uses and Disclosures of PHI
    - Your policy for the disposal of PHI created, received, or maintained by organization
    - Protocols for training all Workforce Members involved in handling and disposing of PHI to ensure compliance with all P&Ps
    - Review and update as necessary, policy for the physical safeguarding of PHI
    - Protocols for training Workforce Members involved with handling PHI to ensure compliance with P&Ps
    - Application of appropriate sanctions against Workforce Members who fail to comply with P&Ps

#### ➤ Leadership

- ✓ Designate, and notify HHS of, a Privacy Officer responsible for development, distribution, and implementation of P&Ps
  - \*Write this into their job description*
- ✓ Designate, and notify HHS of, a contact person/office responsible for receiving complaints regarding violations and can answer questions about the Notice of Privacy Practices §164.52
  - \*Write this into their job description*

### Within 30 days of HHS approval of P&Ps (dependent on length of time it takes HHS to approve)

#### ➤ Policies and Procedures

- ✓ Distribute all P&Ps to Workforce Members and relevant Business Associates (BAs)
  - \*Need to define your “workforce” (not as easy as it seems)*
  - \*Need to define your “relevant BAs” (not as easy as it seems)*
- ✓ Distribute all P&Ps to all new Workforce Members within 30 days of hire

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- ✓ With distribution must obtain a signed written/electronic initial “Compliance Certification” from all Workforce Members, new Workforce Members, and relevant BAs
    - “I have read, understand, and shall abide by such P&Ps”
    - Confirm that they have received the training and the specific date
- \*Create a solid process for obtaining and retaining all “Compliance Certifications”*

#### **After HHS approval of P&Ps**

##### ➤ **Reportable Events**

- ✓ Promptly investigate upon receiving information that a Workforce Member, or a BA, may have failed to comply with P&Ps for safeguarding PHI. If it is determined, after review and investigation, that a Workforce Member has failed to comply, or BA has failed to comply with the requirements in its BAA, notify HHS **within 30 days**.
    - \*This means your BAAs must have the appropriate language requiring them to notify you of a Reportable Event*
    - \*Clearly, you also need an accurate process to capture, track, document and monitor potential Reportable Events.*
    - \*Need a “Reportable Events” P&P*
  - ✓ Reportable Events to HHS must include:
    - A complete description of the Event including relevant facts, persons involved, provision of P&Ps implicated
    - A description of action taken and further steps you plan to take to address the matter to mitigate any harm, and to prevent it from recurring, including application of appropriate sanctions against Workforce Members who failed to comply with HIPAA Privacy P&P.
- \*My understanding is that Reportable Events include any violation of HIPAA P&Ps, not just those associated with the causes for this Resolution Agreement, i.e., disposal of PHI*

#### **Within 60 days after HHS approval of P&Ps**

##### ➤ **Training Materials**

- ✓ Within 60 days of approval of your P&Ps by HHS, provide training materials for all Workforce Members to HHS
- ✓ If HHS has recommended changes to training materials = 30 days to revise and resubmit to HHS for approval
- ✓ Provide training to new Workforce Members and Relevant BAs within 30 days of their beginning of services (*the requirement for training of BAs does not appear to be clear – is annual education required for BAs?*)
- ✓ Obtain “Training Certification” from each Workforce Member (written or electronic) verifying they have attended training. The “Training Certificate” must specify the specific date the training was received.

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#### ➤ **Training**

- ✓ Within 60 days after HHS approval of the training materials, provide training for each Workforce Member
  
- ✓ Provide training to all Workforce Members every 12 months thereafter

#### **120 days after HHS approval of P&Ps**

#### ➤ **Implementation Report**

- ✓ Submit to HHS a written report summarizing the status of its implementation of the requirements of the CAP to include:
  - An attestation signed by an owner or officer of organization attesting that:
    - the P&Ps are being implemented, have been distributed to all appropriate members of the workforce and relevant BAs and that you have obtained all the Certifications required
    - all Workforce Members and Relevant Business Associates have completed the initial training required by this CAP and have executed the training certifications required
    - they have reviewed the Implementation Report, made a reasonable inquiry regarding its content and believe that, upon such inquiry, the information is accurate and truthful
  - A copy of all training materials used for the training required by the CAP, a description of the training, including a summary of topics covered, length of sessions and a schedule of when the training sessions were held

#### **Annually, and as needed**

#### ➤ **Annual Report**

- ✓ One year after the Effective Date and each subsequent 1-year period during the course of the Compliance Term is a Reporting Period. Within 60 days of the close of the Reporting Period, submit an Annual Report to HHS regarding compliance with the CAP to include:
  - A copy of the schedule, topic outlined and training materials for the training programs providing during the Reporting Period
  - A summary of the Reportable Events, if any, the status of any corrective and preventative action (s) relating to all such Reportable Events, or an attestation signed by an officer or director stating no Reportable Events occurred during the Compliance Term.
  - An attestation signed by an officer or director attesting:
    - The organization is obtaining and maintaining written or electronic Training Certifications from all persons who are required to attend training under the CAP
    - That any revision(s) to the P&Ps required were finalized and adopted within 30 days of HHS’s approval of the revision(s), which shall include a statement affirming

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that the organization distributed the revised P&Ps to all appropriate Workforce Members within 60 days of HHS’ approval of the revisions

- That they have reviewed the Annual Report, have made a reasonable inquiry regarding the content and believes that, upon such inquiry, the information is accurate and truthful

#### ➤ **Policies and Procedures**

- ✓ Assess, update, and revise, as necessary, the P&Ps, or as needed
- ✓ If any substantive changes are made, must submit to HHS within 30 days of effective date of substantive revisions
- ✓ Once HHS approves of changes to P&Ps, must redistribute revised P&Ps to all members of the workforce and BAs, to also include “Compliance Certifications”

#### ➤ **Training**

- ✓ Review training materials at least annually and, where appropriate, update the training to reflect changes in Federal law of HHS guidance, any issues discovered during audits or reviews, and any other relevant developments.

#### **Other**

##### ➤ **Document Retention**

Organization shall maintain for inspection and copying, and shall provide to HHS, upon request, all documents and records relating to compliance with the CAP for 6 years from the Effective Date.

##### ➤ **Breach Provisions**