

HIPAA Update/OCR Enforcement
Hand Out Packet

Health Care Compliance Association
HCCA Regional Conference
East Central Region

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U.S. Department of Health & Human Services

Improving the health, safety, and well-being of America

Health Information Privacy

Resolution Agreement

Massachusetts General Hospital Settles Potential HIPAA Violations

The General Hospital Corporation and Massachusetts General Physicians Organization, Inc. (Mass General) has agreed to pay the U.S. government \$1,000,000 to settle potential violations of the HIPAA Privacy Rule.

Mass General, one of the nation's oldest and largest hospitals, signed a Resolution Agreement with HHS that requires it to develop and implement a comprehensive set of policies and procedures to safeguard the privacy of its patients. The settlement follows an extensive investigation by OCR.

"We hope the health care industry will take a close look at this agreement and recognize that OCR is serious about HIPAA enforcement. It is a covered entity's responsibility to protect its patients' health information," said OCR Director Georgina Verdugo.

The incident giving rise to the agreement involved the loss of protected health information (PHI) of 192 patients of Mass General's Infectious Disease Associates outpatient practice, including patients with HIV/AIDS. OCR opened its investigation of Mass General after a complaint was filed by a patient whose PHI was lost on March 9, 2009. OCR's investigation indicated that Mass General failed to implement reasonable, appropriate safeguards to protect the privacy of PHI when removed from Mass General's premises and impermissibly disclosed PHI potentially violating provisions of the HIPAA Privacy Rule.

This impermissible disclosure involved the loss of documents consisting of a patient schedule containing names and medical record numbers for a group of 192 patients, and billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis and name of providers for 66 of those patients. These documents were lost on March 9, 2009, when a Mass General employee, while commuting to work, left the documents on the subway train. The documents were never recovered.

"To avoid enforcement penalties, covered entities must ensure they are always in compliance with the HIPAA Privacy and Security Rules," said Verdugo. "A robust compliance program includes employee training, vigilant implementation of policies and procedures, regular internal audits, and a prompt action plan to respond to incidents."

Additional Information

- ▶ [Read the Resolution Agreement and CAP](#)
- ▶ [Read the HHS Press Release](#)

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RESOLUTION AGREEMENT

I. Recitals

1. Parties. The Parties to this Resolution Agreement (“Agreement”) are the United States Department of Health and Human Services, Office for Civil Rights (“HHS”), and The General Hospital Corporation and Massachusetts General Physicians Organization, Inc. (hereinafter collectively referred to as Massachusetts General Hospital (“MGH”)), each of which is a nonprofit corporation organized and operating under the laws of The Commonwealth of Massachusetts. MGH and HHS shall together be referred to as the “Parties.”

2. Factual Background and Covered Incident.

A. Authority of HHS

HHS 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”) and 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.”). HHS has the authority to conduct investigations of complaints alleging violations of the Privacy and Security Rules by covered entities, and covered entities must cooperate with HHS’ investigation. 45 C.F.R. §160.306(c) and §160.310(b).

B. Covered Incident

The following incident is hereafter referred to as the “Covered Incident”:

(1) On March 6, 2009, an MGH employee removed from the MGH premises documents containing protected health information (“PHI”). The MGH employee removed the PHI from the MGH premises for the purpose of working on the documents from home. The documents consisted of billing encounter forms containing the name, date of birth, medical record number, health insurer and policy number, diagnosis and name of provider of 66 patients and the practice’s daily office schedules for three days containing the names and medical record numbers of 192 patients.

(2) On March 9, 2009, while commuting to work on the subway, the MGH employee removed the documents containing PHI from her bag and placed them on the seat beside her. The documents were not in an envelope and were bound with a rubber band. Upon exiting the train, the MGH employee left the documents on the subway train and they were never recovered. These documents contained the PHI of 192 individuals.

3. No Admission. This Agreement is not an admission, concession, or evidence of liability or wrongdoing by MGH or of any fact or any violation of any law, rule, or regulation, including any violation of HIPAA or the Privacy Rule. This

Agreement is made without trial or adjudication of any alleged issue of fact or law and without any finding of liability of any kind, and MGH's agreement to undertake any obligation under this Agreement shall not be construed as an admission of any kind.

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

5. Intention of Parties to Effect Resolution. This Agreement is intended to resolve the Office for Civil Rights Complaint No. 09-96024, and any violations of the HIPAA Privacy and Security Rules related to the Covered Incident. In consideration of the Parties' interest in avoiding the 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. MGH agrees to pay HHS the amount of \$1,000,000 (Resolution Amount). MGH agrees to pay the Resolution Amount by (1) certified check made payable to "United States Department of Health and Human Services"; or (2) electronic funds transfer pursuant to written instructions to be provided by HHS. MGH agrees to make this payment contemporaneously with its execution of this Agreement.

7. Corrective Action Plan. MGH 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 MGH breaches the CAP, and fails to cure the breach as set forth in the CAP, then MGH will be in breach of this Agreement and HHS will not be subject to the terms and conditions in the Release set forth in paragraph 8 of this Agreement.

8. Release by HHS. In consideration of and conditioned upon MGH's performance of its obligations under this Agreement, HHS releases MGH and its successors, transferees, assigns, and subsidiaries, including its members, officers, agents, directors, affiliates and employees, from any claims and causes of action it has or may have against MGH under the Privacy and Security Rules arising out of or related to the Covered Incident identified in paragraph 2 above. HHS does not release MGH from, nor waive, any rights, obligations, or causes of action other than those arising out of or related to the Covered Incident 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 Party. MGH 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. MGH 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 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 MGH and its successors, 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 the preparation and performance of this Agreement.

12. No Additional Releases. This Agreement is intended to be for the benefit of the Parties only. By this instrument, the Parties do not release any claims against 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 must be set forth in writing and signed by both Parties. Nothing in this Agreement is intended to, or shall, be used as any basis for the denial of any license, authorization, approval, or consent that MGH may require under any law, rule, or regulation.

14. Execution of Agreement and Effective Date. The Agreement shall become effective (*i.e.*, final and binding) upon the date of signing of both 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 must be imposed within six 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, MGH agrees that the time between the Effective Date of this Resolution Agreement (as set forth in paragraph 14) and the date same may be terminated by reason of MGH'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. MGH waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Incident identified in paragraph 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 Resolution Agreement.

16. Disclosure. HHS places no restriction on the publication of the Agreement. This Agreement and information related to this Agreement may be made public by either Party. 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, 5 U.S.C. § 552 (FOIA), and its implementing regulations, 45 C.F.R. Part 5; provided, however, that HHS will use its best efforts to prevent the disclosure of information, documents, and any other item produced by MGH to HHS as part of HHS' review, to the extent such items constitute trade secrets and/or confidential commercial or

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financial information that is exempt from turnover in response to a FOIA request under 45 C.F.R. § 5.65, or any other applicable exemption under FOIA and its implementing regulations.

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 individuals signing this Agreement on behalf of MGH represent and warrant that they are authorized by MGH to execute this Agreement on its behalf. The individual signing this Agreement on behalf of HHS represents and warrants that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

For The General Hospital Corporation

/s/ _____ 2/14/11
Peter L. Slavin, M.D. _____ Date _____
President

For Massachusetts General Physicians Organization, Inc.

/s/ _____ 2/14/11
David Torchiana, M.D. _____ Date _____
Chairman and Chief Executive Officer

For Department of Health and Human Services

/s/ _____ 2/14/11
Peter K. Chan _____ Date _____
Regional Manager, Region I
Office for Civil Rights

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE GENERAL HOSPITAL CORPORATION
AND
MASSACHUSETTS GENERAL PHYSICIANS ORGANIZATION, INC.

I. PREAMBLE

The General Hospital Corporation and Massachusetts General Physicians Organization, Inc. (hereinafter collectively referred to as Massachusetts General Hospital (MGH)) 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, MGH is entering into a Resolution Agreement (Agreement) with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. MGH enters into this CAP as part of the consideration for the release set forth in paragraph 8 of the Resolution Agreement.

II. CONTACT PERSONS AND SUBMISSIONS

A. Contact Persons

MGH has identified the following individuals as its authorized representatives and contact persons regarding the implementation of this CAP and for receipt and submission of notifications and reports:

Deborah Adair
Director, Health Information Services
Privacy Officer
The Massachusetts General Hospital
55 Fruit Street
Boston, MA 02114
Telephone: 617-726-2465

Brent L. Henry, Esq.
Vice President and General Counsel
Partners HealthCare System, Inc.
Office of the General Counsel
50 Staniford Street, 10th Floor

Boston, MA 02114
bhenry1@partners.org
Telephone: 617-278-1115
Facsimile: 617-236-8563

For communications with the Monitor:

Robert Damiano
Director, Internal Audit Services
Partners HealthCare System, Inc.
Internal Audit Services
529 Main Street, Suite 51
Charlestown, MA 02129
rdamiano@partners.org
Telephone: 617-726-8126
Facsimile: 617-724-8039

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

Susan Rhodes, Deputy Regional Manager
Office for Civil Rights, Region I
Department of Health and Human Services
JFK Federal Building, Room 1875
Boston, MA 02203
susan.rhodes@hhs.gov
Telephone: 617-565-1347
Facsimile: 617-565-3809

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

B. Proof of Submissions. Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, other than email, 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. TERM OF CAP

The period of compliance obligations assumed by MGH under this CAP shall begin on the Effective Date and conclude 3 years from the Monitor Plan Approval Date pursuant to section V.E.2., except that after this period MGH shall be obligated to: (a) submit the Annual Report for the final Reporting Period, as set forth in section VI.B.; and (b) comply with the document retention requirement set forth in section VII. The Effective Date shall be calculated in accordance with paragraph 14 of the Resolution Agreement.

IV. TIME

In computing any period of time prescribed or allowed by this CAP, 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 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

MGH agrees to the following:

A. Policies and Procedures

1. MGH shall develop, maintain, and revise, as necessary, written policies and procedures governing (i) physical removal and transport of Protected Health Information (PHI), (ii) laptop encryption, and (iii) USB drive encryption (collectively, Policies and Procedures) that: (a) address the Covered Incident specified in paragraph 2 of the Agreement; and (b) are consistent with the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A, C, and E of Part 164, the Privacy and Security Rules). Policies and Procedures shall include the minimum content set forth in section V.C. Policies and Procedures required under this CAP are in addition to, and may be incorporated into, any policies and procedures required by the Privacy and Security Rules.

2. MGH shall provide such Policies and Procedures, consistent with paragraph 1 above, to HHS within 90 days of the Effective Date for review and approval. Upon receiving any required changes to such Policies and Procedures from HHS, MGH shall have 60 days to revise such Policies and Procedures accordingly, and provide the revised Policies and Procedures to HHS for review and approval, which shall not be unreasonably withheld.

3. MGH shall fully implement its Policies and Procedures within 90 days of HHS' approval of the Policies and Procedures as described in section V.A.2. MGH's Policies and Procedures shall not be deemed fully implemented unless MGH has provided the specific training as required in the first paragraph of section V.D.1.

B. Distribution and Updating of Policies and Procedures

1. Within 30 days of HHS' approval of the Policies and Procedures identified in section V.A., MGH shall distribute such Policies and Procedures to all members of the workforce who have access to and use PHI. MGH shall distribute the Policies and Procedures to new members of the workforce who have access to and use PHI within 15 days of the workforce members beginning their service.

2. MGH shall document distribution of the Policies and Procedures and require, in connection with the distribution, workforce members to read and abide by

such Policies and Procedures. Such documentation shall be retained by MGH and made available to HHS pursuant to sections V.E.5. and VII. MGH shall attest in the Implementation Report that the Policies and Procedures were distributed to the workforce members.

3. MGH shall assess, update, and revise, as necessary, the Policies and Procedures at least annually (and more frequently if appropriate). MGH shall provide such revised Policies and Procedures to HHS for review and approval. Upon receiving any required changes to such revised Policies and Procedures from HHS, MGH shall have 30 days to adopt such changes accordingly, and provide the revised Policies and Procedures to HHS for review and approval, which shall not be unreasonably withheld. Within 30 days of HHS' approval of any substantive revisions, MGH shall distribute such revised Policies and Procedures to all members of its workforce who have access to and use PHI. MGH shall fully implement the revised Policies and Procedures within 60 days of its receipt of HHS' approval.

C. Minimum Content of the Policies and Procedures

The Policies and Procedures shall, at a minimum, include:

1. The administrative, physical, and technical safeguards in the Privacy and Security Rules that relate to the Policies and Procedures and reasonable protections for such PHI from any intentional or unintentional uses or disclosures in violation of the Privacy Rule.

2. If MGH determines that a member of their workforce has violated these Policies and Procedures, MGH shall notify in writing the Monitor described in section V.E. within 30 days of its determination. Such violations shall be known as Reportable Events. The report to the Monitor shall include the following information:

- a. A complete description of the event, including the relevant facts, the persons involved, and the provision(s) of the Policies and Procedures implicated;
- b. A description of MGH's actions taken to mitigate any harm and any further steps MGH plans to take to address the matter and prevent it from recurring.

D. Training

1. Specific Training. Within 90 days of HHS' approval of the Policies and Procedures identified in section V.A., MGH shall provide specific training on the Policies and Procedures to all workforce members who have access to and use PHI.

After HHS' approval of the Policies and Procedures, MGH shall provide such training to new members of the workforce who are engaged in the above-referenced activities within 30 days of the workforce members beginning their service.

2. Training Certification. Each workforce member who is required to attend training shall certify, in writing or in electronic form, that the workforce member has received the required training. The training certification shall specify the date training was completed. All course materials shall be retained in compliance with section VII.

3. Annual Review of Training. MGH shall review the training annually, and update the training to reflect any new changes in federal law or HHS guidance or substantive revisions to the Policies and Procedures.

4. Prohibition on Removing PHI from Premises. Except as provided in section V.D.5., MGH shall prohibit any member of its workforce from physically removing PHI from MGH premises for use off-site and/or transporting PHI off-site if that workforce member has not completed a specified training certification required by section V.D.2.

5. Exception to Prohibition in V.D.4. MGH may permit workforce members to physically remove PHI from MGH premises for use or transport off-site provided that MGH, immediately following the Effective Date, has distributed a communication to its workforce members informing them that: (a) MGH has entered into this CAP with HHS; (b) pursuant to this CAP, MGH will be distributing new or revised Policies and Procedures relating to the physical removal of PHI from MGH premises and providing mandatory training to the workforce with respect to the Policies and Procedures; (c) workforce members may physically remove PHI from MGH premises only for the performance of their job duties and, when removing PHI, shall take reasonable and appropriate steps to safeguard its confidentiality; and (d) workforce members who fail to reasonably and appropriately safeguard such PHI are subject to sanctions (the "Communication"). This exception to the prohibition in section V.D.4. expires on completion of the 90 day period or the specific training required by the first paragraph in section V.D.1., whichever is sooner, for those workforce members who have not completed a specified training certification required by section V.D.2.

6. Distribution of the Communication. The Communication, as described in section V.D.5., shall be distributed by email to the workforce members from the President or Chief Executive Officer of MGH with a copy to MGH's Privacy Officer. MGH shall provide a copy of the Communication to HHS promptly upon distribution. Department managers shall confirm to the Privacy Officer within a reasonable time following distribution of the Communication that workforce members under their supervision have received and read the Communication. The Privacy Officer then shall promptly provide a written attestation to HHS confirming that the Department managers have provided the confirmations described in the foregoing sentence.

E. Monitoring

1. Designation of Monitor. MGH shall designate the individual serving as the Director of Internal Audit Services of the Partners HealthCare System, Inc. at the time of the Effective Date as the Monitor under this CAP. The Monitor must certify in writing at the time of his designation, and must provide reasonable written documentation, to the

effect that he has the requisite expertise and experience regarding the implementation of the Privacy and Security Rules and has the necessary resources and is otherwise able to perform the reviews described herein in a professionally independent fashion, taking into account any other business relationships or other engagements that the individual may have.

Upon reasonable notice, HHS may interview the individual who is designated by MGH as the Monitor. MGH shall provide the Monitor with convenient, timely access to any workforce members, policies, procedures, audit records, or other items or information that the Monitor deems necessary for the review and performance of the Monitor's duties.

2. Description of Monitor's Duties. The Monitor shall conduct assessments of implementation and compliance by MGH with the Corrective Action Obligations set forth in section V. hereof and prepare the plan and reports described below.

Within 45 days of the Effective Date, the Monitor shall submit to HHS and MGH a written plan, describing with adequate detail, the Monitor's plan for fulfilling the duties set forth in this section V.E. (Monitor Plan).

Within 45 days of its receipt of the Monitor Plan, HHS shall inform MGH and the Monitor of its approval or disapproval of the proposed Monitor Plan. If HHS does not approve the proposed Monitor Plan, HHS shall set forth in writing the reasons for its disapproval and required revisions to the proposed Monitor Plan, which shall be reasonable and consistent with this CAP. The Monitor then shall submit a revised Monitor Plan to HHS, incorporating HHS' comments and required revisions, within 30 days of the date that HHS informed the Monitor of its disapproval of the proposed Monitor Plan. HHS shall inform MGH and the Monitor of its approval or disapproval of the revised Monitor Plan within 30 days of its receipt of the revised Monitor Plan (Monitor Plan Approval Date).

The Monitor shall review the Monitor Plan at least annually and shall provide HHS and MGH with a copy of any revisions to the Monitor Plan, before they are incorporated, for approval by HHS. HHS shall inform MGH and the Monitor of its approval or disapproval of the revisions. If HHS does not approve the proposed revisions, HHS shall set forth in writing the reasons for its disapproval and required modifications, which shall be reasonable and consistent with this CAP. The Monitor then shall timely incorporate the modifications into the Monitor Plan.

The Monitor shall begin implementation of the Monitor Plan immediately after the Monitor Plan Approval Date. Whenever the existing Monitor Plan is updated or revised and the updated or revised version has been approved by HHS and has then gone into effect, the updated or revised Monitor Plan shall supersede the prior Monitor Plan.

- a. The Monitor shall review MGH's compliance with this CAP and shall seek to validate that:

- i. All members of MGH's workforce are trained and familiar with the Policies and Procedures; and
 - ii. All members of MGH's workforce are complying with the Policies and Procedures.
- b. The Monitor shall conduct his reviews and shall assess compliance by MGH with its obligations relative to the established processes and timeframes for satisfying such obligations under the CAP in accordance with the Monitor Plan. Monitor reviews shall include, but not be limited to:
 - i. unannounced site inspections of MGH's locations/departments/practices referenced in section VI.A.4.;
 - ii. interviews with any members of the workforce who use PHI;
 - iii. interviews with any members of the workforce involved in implementing the safeguards required by this CAP;
 - iv. inspection of a sample of laptops and USB flash drives that contain ePHI and are under the control of workforce members to ensure that such devices satisfy all applicable requirements of the Policies and Procedures; and
 - v. inspection of relevant documents and interviews with workforce members for the purpose of confirming consistent training, implementation, and enforcement of the Policies and Procedures among workforce members.
- c. Semi-Annual Monitor Reports. Within 180 days of the Monitor Plan Approval Date, and once every 6 month period thereafter, the Monitor shall prepare a written report based on the reviews the Monitor has performed and provide such report to HHS and MGH (Monitor Report). The Monitor Report shall describe Reportable Events in the manner set forth in sections V.C.2.a. and V.C.2.b. that relate to impermissible uses and disclosures of PHI. The Monitor Report shall include a summary of all other Reportable Events. MGH shall prepare a response to the Monitor Report and provide such response to HHS and the Monitor within 30 days of MGH's receipt of the Monitor Report.
- d. Monitor Reports Regarding Violation(s). The Monitor shall report any significant violations of the CAP to HHS and MGH within 10 business days of the Monitor's discovery of such violation. MGH shall prepare a response, including a plan of correction, and provide such response to HHS and the Monitor within 10 business days of its receipt of the Monitor's report of a significant violation.

e. Documentation of Monitor Reviews. The results of Monitor reviews shall be fully documented, including, but not limited to,

- i. Dates of unannounced site visits;
- ii. Summaries of results of interviews; and
- iii. Summaries of inspections of laptops and USB flash drives.

3. Validation Review. If HHS has reason to believe that (a) the Monitor's reviews or reports fail to conform to the requirements of this CAP or (b) the Monitor's report results are inaccurate, HHS may unilaterally conduct its own review to determine whether the Monitor reviews or reports complied with the requirements of the CAP and/or are inaccurate ("Validation Review").

4. Monitor Replacement.

a. MGH Replaces Monitor. If MGH intends to replace a Monitor during the term of this CAP, MGH shall immediately submit a notice explaining its reasons to HHS before doing so, unless exigent circumstances require immediate replacement. MGH shall propose a new internal Monitor without unreasonable delay and shall designate the new Monitor, subject to approval by HHS which shall not be unreasonably withheld.

b. HHS Replaces Monitor. If HHS has a reasonable basis to conclude that a Monitor does not possess the expertise, independence, or objectivity necessary to perform the duties under this CAP, or has failed to carry out the Monitor's responsibilities as set forth in this CAP, HHS shall notify MGH of its intent to replace the Monitor and provide a written explanation to MGH of its reasons for requiring MGH to designate a new Monitor. Within 15 days following MGH's receipt of such notice (or such additional period as the Parties may agree) (the "Period"), appropriate representative(s) of MGH and HHS shall meet to discuss in good faith and, if possible, resolve the concerns set forth in HHS' notice. If HHS' concerns are not resolved through this informal process, then at the conclusion of the Period, HHS may unilaterally require MGH to designate a new internal Monitor. In such event, MGH shall propose a new Monitor without unreasonable delay and shall designate a new Monitor, subject to approval by HHS which shall not be unreasonably withheld.

c. HHS Approval Criteria. HHS' approval of a new Monitor shall be based on the expertise and experience regarding the implementation of the Privacy and Security Rules and whether in HHS' determination the new Monitor has the necessary resources and is otherwise able to perform the reviews described herein in a professionally independent fashion, taking into account any other business relationships or other engagements that the individual may have.

d. Monitor Certifies Credentials. The Monitor must certify in writing at the time of his or her designation, and must provide reasonable written documentation, to the effect that he or she has the requisite expertise and experience regarding the implementation of the Privacy and Security Rules and has the necessary resources and is otherwise able to perform the reviews described herein in a professionally independent fashion, taking into account any other business relationships or other engagements that the individual may have.

e. MGH agrees to bear all of its costs incurred related to the Monitor, including, but not limited to, costs associated with a Monitor's replacement and the performance of a Monitor's duties under this CAP.

5. Retention of Records. The Monitor and MGH shall retain and promptly make available to HHS, upon request, all non-privileged work papers, supporting documentation, correspondence, and draft reports (those exchanged between the Monitor and MGH) related to the reviews by the Monitor in accordance with the CAP. If MGH asserts a claim of privilege with respect to any document that HHS requests MGH to make available for inspection and copying under this section, within a reasonable time of such request, MGH shall prepare a log identifying the document and the type of privilege asserted (e.g., attorney-client privilege, attorney work product, patient confidentiality, or other privilege). MGH shall make the log available to the Monitor, who shall provide it to HHS promptly upon request.

6. The use of a monitor does not affect HHS' authority to investigate complaints, or conduct compliance reviews or audits, or MGH's compliance with 45 C.F.R. Part 160, Subpart C.

VI. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after receiving HHS' approval of the Policies and Procedures required by section V.A., MGH shall submit a written report to HHS and the Monitor summarizing the status of its implementation of the requirements of this CAP. This report, known as the "Implementation Report," shall include:

1. An attestation signed by an officer of MGH attesting that the Policies and Procedures were fully implemented within 90 days of HHS' approval of the Policies and Procedures, which shall include a statement affirming that MGH distributed the Policies and Procedures to all appropriate members of the workforce within 30 days of HHS' approval;

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 session(s) were held;

3. An attestation signed by an officer of MGH attesting that members of the workforce who were scheduled to complete the training required by section V.D.1. of this CAP by the date of this Implementation Report have completed such training and have executed the training certifications required by section V.D.2.;

4. An attestation signed by an officer of MGH listing all MGH's locations/departments/practices (including mailing addresses), the name under which each location is doing business, the corresponding phone numbers and fax numbers, and attesting that each location is in compliance with the obligations of this CAP; and

5. An attestation signed by an officer of MGH stating that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports. The one-year period after the Effective Date and each subsequent one-year period or portion thereof during the course of the period of compliance obligations shall be known as a "Reporting Period." MGH shall submit Annual Reports to the Monitor that reflect its status in complying with this CAP for each Reporting Period. Such Annual Reports shall be incorporated into the Monitor Reports to HHS. MGH shall submit each Annual Report to the Monitor no later than 60 days after the end of each corresponding Reporting Period. The Annual Report shall include:

1. A copy of the schedule, topic outline, and materials for the training programs provided during the Reporting Period that is the subject of the report;

2. An attestation signed by an officer of MGH attesting that MGH obtains and maintains written or electronic training certifications from all persons that must attend training, and that such training complies with the requirements established under this CAP;

3. An attestation signed by an officer of MGH attesting that any revision(s) to the Policies and Procedures under section V.B.3. were fully implemented within 60 days of HHS' approval of the revision(s), which shall include a statement affirming that MGH distributed the revised Policies and Procedures to all appropriate members of the workforce within 30 days of HHS' approval of the revision(s);

4. A summary of Reportable Events (defined in section V.C.2.) that occurred during the Reporting Period and the status of any corrective and preventative action(s) relating to all such Reportable Events;

5. A copy of reports generated by Monitor reviews pursuant to section V.E.2;
and

6. An attestation signed by an officer of MGH 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 and truthful.

VII. DOCUMENT RETENTION

The office(s) responsible for implementation of the obligations of the CAP shall maintain, for the individuals holding the titles set forth herein, for inspection and copying all non-privileged documents and records relating to compliance with this CAP for 6 years from the Effective Date. If MGH asserts a claim of privilege with respect to any document that HHS requests MGH to make available for inspection and copying under this section, within a reasonable time of such request, MGH shall prepare a log identifying the document and the type of privilege asserted (e.g., attorney-client privilege, attorney work product, patient confidentiality, or other privilege). MGH shall make the log available to the Monitor, who shall provide it to HHS promptly upon request.

VIII. REQUESTS FOR EXTENSION AND BREACH PROVISIONS

MGH is expected to fully comply with all provisions contained in this CAP.

A. Timely Written Requests for Extensions. MGH, through the Monitor, in advance of any due date set forth in this CAP, may 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 ten (10) business days prior to the date by which any act is due to be performed or any notification or report is to be filed and must contain a description of the facts giving rise to the request. HHS will consider such a request and make a reasonable determination as to whether to grant it.

B. Notice of Breach. The Parties agree that an uncured breach of this CAP by MGH – meaning a breach of this CAP by The General Hospital Corporation or Massachusetts General Physicians Organization, Inc. – constitutes a breach of the Resolution Agreement. MGH agrees that actions or omissions of the Monitor in his or her performance of the duties set forth in section V.E.2. shall be deemed actions or omissions of MGH. Upon a determination by HHS that MGH has breached this CAP, HHS will notify MGH of MGH’s breach thereof (this notification is hereinafter referred to as the “Notice of Breach”).

C. MGH Response. MGH shall have 30 days from the date of receipt of the Notice of Breach to demonstrate to HHS’ satisfaction that:

1. MGH is in compliance with the obligations of the CAP cited by HHS as the basis for the breach; or
2. the alleged breach has been cured; or
3. the alleged breach cannot be cured within the 30-day period, but that: (i) MGH has begun to take action to cure the breach; (ii) MGH is pursuing such action with due diligence; and (iii) MGH has provided to HHS a reasonable timetable for curing the breach.

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D. Imposition of CMP. If at the conclusion of the 30-day period, MGH fails to meet the requirements of section VIII.C. to HHS' satisfaction, HHS may proceed to impose a civil money penalty (CMP) on MGH pursuant to 45 C.F.R. Part 160 for violations of the Privacy Rule related to the Covered Incident set forth in paragraph 2 of the Resolution Agreement and for any other act or failure to act that constitutes a violation of the Privacy Rule or Security Rule. HHS shall notify MGH in writing of its determination to proceed with the imposition of a CMP. MGH will retain all of the rights and obligations specified under 45 CFR Part 160, Subparts C through E, with respect to any determination by HHS that MGH has violated the Privacy Rule or the Security Rule and with respect to the imposition of a CMP under this paragraph.

For The General Hospital Corporation

/s/

2/14/11

Peter L. Slavin, M.D.
President

Date

For Massachusetts General Physicians Organization, Inc.

/s/

2/14/11

David Torchiana, M.D.
Chairman and Chief Executive Officer

Date

For Department of Health and Human Services

/s/

2/14/11

Peter K. Chan
Regional Manager, Region I
Office for Civil Rights

Date