The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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MEMORANDUM: MASS COMM POST-RANDOMIZATION PHASE COHORT STUDY

TO: Chief Executive Officers, Principal Investigators and Data Managers for Non-Surgery-on-Site Hospitals participating in the MASS COMM Post-Randomization Phase Cohort Study

FROM: Madeleine Biondolillo, MD, Director
Bureau of Health Care Safety and Quality

DATE: July 31, 2013

RE: Close-out of the MASS COMM Post-Randomization Phase Cohort Study

The Department of Public Health is formally ending the MASS COMM Post-Randomization Phase Cohort Study (the Cohort Study). The nine non-surgery-on-site (non-SOS) hospitals that have participated in the MASS COMM Trial should stop enrollment of patients in the Cohort Study on July 31, 2013; hospitals shall not enroll patients undergoing non-emergency percutaneous coronary intervention (PCI) on or after August 1, 2013 in the study. Each hospital must complete the data submissions for all enrolled Cohort Study patients to the Harvard Clinical Research Institute (HCRI), including the 30-day follow-up data.

These same hospitals may continue to provide *non-emergency* angioplasty under a waiver of the Department of Public Health's (DPH or the Department) hospital licensure regulation 105 CMR 130.975(B)(1), which allows only hospitals with cardiac surgery on-site to perform PCI. The continuation of this waiver is contingent upon:

1. Adherence to the revised inclusion/exclusion criteria for all non-emergency angioplasty patients (Attachment A). These criteria were developed by a group of clinical experts representing both SOS and non-SOS hospitals.

2. Cooperation with the close-out activities performed by HCRI, including site monitoring, data queries, source document submission, etc., as well as timely payment

for all data collection, processing, monitoring and reporting associated with all enrolled patients, as stipulated in the hospital contracts with HCRI;

3. Execution of a revised collaboration agreement with at least one surgery-on-site (SOS) hospital by August 15, 2013. The current collaboration agreements are specific to non-emergency angioplasty patients participating in the MASS COMM Trial and primary angioplasty special project patients. Hospitals must revise these collaboration agreements to apply to all angioplasty patients. A hospital can use the same collaboration agreement to cover both primary and non-emergency angioplasty patients, but the agreement must clearly state that all primary angioplasty patients are participating in the Primary Angioplasty Special Project;

4. Creation and implementation of a revised informed consent document to replace the current informed consent documents, which are specific to participation in the MASS COMM Trial. A hospital can use the same informed consent document to cover both primary and non-emergency angioplasty patients, but the document must clearly state that the hospital does not have cardiac surgery on site, and that all primary angioplasty patients are participating in the Primary Angioplasty Special Project;

5. Monthly submission to DPH of information regarding sentinel events (as described below);

6. Compliance with the hospital cardiac catheterization service licensure regulations at 105 CMR 130.900 through 130.982. During the Trial and Cohort Study, participating non-SOS hospitals were not subject to the annual facility PCI volume minimum (200). Beginning with fiscal year 2014 (July 1, 2013-June 30, 2014), non-SOS hospitals performing non-emergency PCI will be subject to the facility PCI volume minimum. Hospitals that wish to request a waiver of any of the requirements at 105 CMR 130.900 through 130.982 may submit a formal waiver request to Gail Palmeri at the address above; and

7. Continued provision of primary angioplasty services, seven days per week, twenty-four hours per day and performance of at least 36 primary angioplasty procedures per year.

Data and Monitoring

Each hospital must continue to submit data to MassDAC for all PCI patients, as required by the hospital licensure regulations at 105 CMR 130.1301 through 130.1303. In addition, for DPH monitoring purposes, the hospitals must notify the Department of sentinel events for non-emergency angioplasty patients. These events include:

- Death, either in the non-SOS hospital or at a SOS hospital to which a non-emergency angioplasty patient has been transferred for further care or treatment,
- Emergency CABG, as defined for the NCDR® CathPCI Registry®,
- Emergency transfer to a surgery-on-site hospital, and
- In-hospital stent thrombosis.

Each hospital must submit this information to DPH on a new excel version (see Attachment B) of the Monthly Primary Angioplasty Procedure Volume Report that the hospitals currently submit each month. Please note that unlike the Monthly Primary Angioplasty Procedure Volume Report, hospitals only need to include those patients who experienced a sentinel event on the Non-Emergency Angioplasty Monthly Sentinel Events Report. **The first sentinel event report for non-emergency angioplasty patients will be due September 1, 2013. This first report should include sentinel event information for non-emergency angioplasty patients for the entire month of August, and should be submitted with the Monthly Primary Angioplasty Procedure Volume Report.**

Each hospital will be subject to unannounced DPH surveys of its angioplasty services. These surveys may involve reviews related to other areas of the hospital.

Should the hospital fail to abide by the requirements as outlined in this memorandum, or other requirements included in the cardiac catheterization service licensure regulations found at 105 CMR 130.900 through 130.982, the waiver to allow the hospital to continue to provide non-emergency angioplasty may be revoked.

The Department is beginning the process of revising its licensure regulation to allow the MASS COMM participant non-SOS hospitals to perform non-emergency angioplasty. The requirements outlined in this memorandum, which are subject to change with notice, will otherwise remain in place until amendments are promulgated.

MASS COMM participant community hospitals that are interested in continuing to provide non-emergency angioplasty should complete and submit the attestation below on or before August 15, 2013. Failure to return the completed attestation to the Department by August 15, 2013 may jeopardize the hospital's ability to continue performing non-emergency PCI.

Should you have questions about this memorandum, please contact Nancy Murphy at 617-753-8120 or Nancy.Murphy2@massmail.state.ma.us.

CC: MASS COMM Executive Operations Committee
Katy Agule, Associate Project Manager, Harvard Clinical Research Institute
Ann Lovett, RN, Program Manager, MassDAC
Anuj Goel, Esq. Sr. Dir., Regulations and Staff Counsel, Massachusetts Hospital Association

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ATTESTATION

_____, located at _____
Hospital Name

_____,

through the submission of this completed attestation requests continuation of the waiver of regulation 105 CMR 130.975(B)(1) to perform non-emergency percutaneous coronary interventions (PCIs), also known as non-emergency angioplasty, without surgery-on-site.

Medical Director of Cardiac Catheterization Service:

_____
First Name **Last Name**

_____
Phone **Fax** **Email**

Principal Nurse: _____
First Name **Last Name**

_____
Phone **Fax** **Email**

Data Coordinator: _____
First Name **Last Name**

_____
Phone **Fax** **Email**

Participating Interventionalists at this hospital:

_____

_____

_____

_____

_____

_____

Corresponding Surgery-on-Site (SOS) Hospital(s):

_____

_____

_____

Check as applicable:

☐ The hospital complies with all cardiac catheterization service licensure regulations. Beginning in FY14, this will include the hospital total PCI volume minimum (200 procedures annually).

☐ The hospital provides primary angioplasty **24 hours per day, seven days per week.**

☐ The hospital attests that the each interventionalist at this site:

- is board certified in interventional cardiology,
- is credentialed at a corresponding surgery-on-site hospital(s).

☐ The hospital attests that all patients undergoing non-emergency PCI meet the most recently issued inclusion and exclusion criteria.

☐ The hospital attests to the implementation of a revised informed consent document specific to non-emergency angioplasty without cardiac surgery on site.

☐ The hospital has a signed agreement with at least one SOS hospital that addresses responsibilities to ensure collaboration regarding optimal patient management strategies, including but not limited to potential patient candidacy for cardiac surgery, management of complications experienced by any non-emergency angioplasty patient during his/her hospital stay and rapid transport for patients for

whom a procedural complication warrants surgical intervention. A copy of each agreement is available for review upon request by the Department.

☐ The hospital agrees to submit all data requested by HCRI, MASS-DAC Data Coordinating Center and the Department of Public Health in a timely manner.

☐ The hospital attests that it will continue to collect and submit the data required for participation in the Department's *primary angioplasty* special project.

Signatures:

Chief Executive Officer:

_____
Print name

_____
Signature Date

Chief of Cardiology or Cardiovascular Services:

_____
Print name

_____
Signature Date

Physician Director of Cardiac Catheterization Service/Interventional Cardiology:

_____
Print name

_____
Signature Date

Return the completed, signed attestation to:
Department of Public Health
Bureau of Health Care Safety and Quality
c/o Nancy Murphy
99 Chauncy Street, 11th fl.
Boston, MA 02111