COBTH
CONFERENCE OF BOSTON TEACHING HOSPITALS

11 Beacon Street, Suite 710
Boston, MA 02108
Phone: 617-723-6100
Fax: 617-723-6111
www.cobth.org

October 31, 2014

Mr. David Seltz, Executive Director
Health Police Commission
Two Boylston Street, 6th Floor
Boston, MA 02116

RE: 958 CMR 7.00 – Notice of Material Change and Cost and Market Impact Reviews

Dear Mr. Seltz:

The Conference of Boston Teaching Hospitals (COBTH) and its member hospitals appreciate this opportunity to provide comments on the Health Policy Commission's (HPC or the Commission) proposed regulations, 958 CMR 7.00, regarding Notices of Material Change (MCN) and Cost Market Impact Reviews (CMIR). These comments are offered in a spirit of cooperation and commitment toward regulations that are consistent with the statue and its legislative intent.

Before identifying specific areas of concern, I would like to point out that by limiting an examination of material change to only the commercial market, the HPC may not get an accurate representation of the health care marketplace. Public payers make up a large portion of the payer mix for each of COBTH's member institutions. As such, to cover public payer cost shortfalls there is a cost shift in the commercial market's relative price. While we recognize the HPC is limited in its access to public payer data, by not accounting for this cost shift the Provider's price and TME may be distorted.

Recommendation for Sub-Regulatory Guidelines

As many of our comments on the proposed regulations request the Commission to provide further clarification on various terms, we recommend that the Commission consider developing sub-regulatory guidance in addition to the proposed regulations in order to address clarification questions that may arise. Such guidance would be a helpful way to provide examples and explanations of certain phrases in the regulations do not require a separate definition yet may not be commonly understood. For example, the following terms would benefit from further HPC clarification:

- "likely to be meaningful to purchasers and Payer networks" – *from the definition of Dispersed Service Are;*
- "significant importance to Payer networks" – *from the definition of Dominate Market Share;*
- "affiliation" – *appearing as an undefined term throughout the definition section as well as in the first and third examples of the definition of Material Change;*
- "significant proportion of its volume" – *from the definition of Primary Service Area;*
- "minimum proportion of the total discharges" – *from the definition of Primary Service Area.*

7.02: Definitions

We appreciate the Commission's expansion of the definition section and the clarification provided therein but, there are several terms where further clarification and modification are necessary.

Corporate Affiliation: We request the Commission clarify the terms 'partial or complete controlling interest' and 'partial or complete common control.'

In the HPC's definition of Corporate Affiliation it is not immediately apparent what the phrases 'partial or complete controlling interest' and 'partial or complete common control' intend to capture. 'Partial control' is not a commonly used phrase and requires further clarification and examples of its materiality and scope. We request the HPC clarify what is intended and not intended by the term 'partial' and consider providing specific examples.

Material Change: We recommend the Commission exclude 'employment' as an example of other Acquisitions, Mergers or Affiliations as it currently appears in subsection (3) of the definition of 'Material Change' or develop a full definition and materiality threshold.

There is shared concern among COBTH members that including 'employment' as an example of "any other acquisition, merger or affiliation" is overly broad. Including 'employment' without a full definition could, for example, capture transactions that have little or no impact on market share or prices. We recommend that the Commission develop a materiality threshold for such anticipated transactions.

Material Change: We request the Commission define and provide examples for the ambiguous terms: 'near-majority,' 'given service,' and 'region,' appearing in the final clause of subsection (3) of the definition for "Material Change."

COBTH and its members would appreciate the Commission to define and provide examples for the terms: 'near-majority,' 'given service,' and 'region,' as they appear in subsection (3) of the definition for "Material Change." While the terms in this clause as well as the clause itself appear in the statute, the legislature did not expressly define the scope of the terms thereby leaving the term open to interpretation.

'Near-majority' is ambiguous, for example, as it could mean exactly forty-nine percent of market share in a given service or region or it could refer to some other majority standard. It is also unclear which 'given service' or services will be used to define one's market share. As a 'near majority' in one 'given service' will define a material change regardless of that Provider's market share in any one or all given services it is crucial to have these terms defined. 'Region' likewise is open to subjective interpretation as it is unclear how the HPC defines a Provider or Provider Organization's service area.

We request the Commission define and provide examples for these terms to remove ambiguity in the definition of 'Material Change.'

Material Change: We recommend the Commission narrow the definition of clinical affiliation to capture only those affiliations which are material and likely to have an impact on cost and market share and/or develop a materiality threshold.

COBTH and its members understand the Commission's inclusion of the statutory definition of clinical affiliation in the regulations however, in context of MCN and CMIR reporting the definition is overly broad, capturing what we consider to be non-material affiliations which fall outside the scope of the legislature's intent.

Further, as written the definition of clinical affiliation captures routine affiliations such as clinical trials and GME programs which do not have a material effect of the market. Likewise many of the other affiliations cited in the definition - enhanced electronic access and communication, joint training programs and video technology – are not likely to have any impact on cost and market share. We recommend the Commission narrow its definition of clinical affiliation to reflect the materiality of the affiliation for the health care market.

Additionally we suggest the Commission develop a materiality threshold. A materiality threshold on the payments between parties for activities related to the clinical affiliation set at either $5 million or $10 million would focus the scope of affiliations evaluated by the Commission and reduce overall administrative burdens for all parties involved.

Material Change: We urge the Commission to develop a more accurate measure of materiality for Clinical Affiliations between Providers than either party's having an annual Net Patient Service Revenue of $25 million or more in subsection (4) of the definition of Material Change.

Subsection (4) defines material change as any clinical affiliation between two providers with more than $25M in net patient service revenue. If the Commission is trying to identify those proposed affiliations that may alter the health care market, impact prices or market chare, we do not believe that the size of the entities entering into a clinical affiliation provides any indication of those potential impacts. As mentioned above many of the affiliations cited in the definition of clinical affiliation are not likely to have any impact on cost, market share and the annual revenue of the affiliates is not relevant. Requiring entities with annual revenue in excess of $25M to file a notice of material change for any clinical affiliation in essence requires **all** proposed clinical affiliations to be reported to the Commission. This would delay many affiliations that the Commission is likely to deem not worthy of further review and add to administrative burden for the proposed affiliates as well as HPC staff.

We urge the Commission to eliminate annual revenue of entities as a trigger for materiality of proposed clinical affiliation, and implement a materiality threshold as suggested above.

Material Change: We recommend the Commission require only one party to a proposed affiliation file an MCN with the HPC as specified under subsection (4) of the definition of Material Change.

When two or more Providers propose an affiliation the draft regulations do not define which party is required to file an MCN with the Commission. The proposed regulations appear to require both/all parties to the agreement to file independent, but duplicative MCNs with the Commission. Such requirement places an undue administrative burden upon the affiliating organizations as well as the Commission who must then compare and contrast the duplicative MCNs. For purposes of

administrative simplicity, we recommend the Commission require only one party to the affiliation to file a notice and require the other party(ies) to attest that the notice is an accurate reflection of the proposed affiliation.

Materially Higher Price & Materially Higher Health Status Adjusted Total Medical Expense: We encourage the Commission to provide greater clarification and specific examples how the HPC defines "similar Providers or Provider types."

Where comparison of "similar Providers or Provider types" influences the determination of a Provider or Provider Organization having a 'Materially Higher Price' or, a 'Materially Higher Health Status Adjusted Total Medical Expense (TME),' our member hospitals would appreciate clarification of what methodology the Commission plans to use to define such parameters. There is concern among our member hospitals that the grouping of similar Providers or Provider types will not accurately capture the unique and specialty services provided at each institution. For example, while COBTH's members all are teaching hospitals they are not all alike. Yet, were they grouped together such comparison would not match like with like potentially resulting in false positives of 'materially higher.' We encourage the HPC to clarify and provide specific examples of its grouping methodology.

Materially Higher Health Status Adjusted Total Medical Expense: We encourage the commission to use the industry standard methodology of 'Standard Deviation' to determine a Provider's Medical Expense rather than adjusting for Health Status.

Where 'Standard Deviation' is the industry's standard method of assessing a Provider's TME we encourage the HPC to follow standard practice and use this method when determining if TME is Materially Higher. There is concern that deviating from the industry's standard and assessing TME as adjusted for health status could potentially result in false positives or negatives.

7.03: Requirement to File a Notice of Material Change; Timing of Filing

(2) Timing of Filing: We encourage the Commission to set a specific time period for requests of additional data during the course of a full CMIR and limit the number of requests for additional information.

We encourage the Commission to be more specific in terms of the process for requesting information and documents from provider organizations that are undergoing full CMIRs. The statute provides the Commission with the ability to request information and documentation above and beyond the preliminary information submitted. However, we are concerned that repeated requests for information during the course of a full CMIR will add delay and unpredictability to an already lengthy process.

While it's reasonable to assume that the Commission might have questions stemming from the information submitted by the provider organization(s) pursuant to the Commission's initial information request, the Commission should limit itself to one follow-up request. Should the Commission have additional requests, such requests should not extend the 185 day timeline for completion of the full review.

7.06: Factors Considered in a Cost and Market Impact Review

(8): We request the Commission to clarify what is meant by the phrase: "methods...to attract patient volume."

We ask the commission to clarify what methods it has in mind that a Provider or Provider Organization uses "to attract patient volume." We are unsure which specific practices the Commission means by this phrase.

7.09: Confidentiality

We request the Commission provide the Provider with advance notice of any intended release of confidential information.

Given the nature of the information Providers and Provider Organizations provide the Commission during an MCN and CMIR, we recommend that the Commission provide advance notice to a Provider prior to any release of redacted confidential information. It is in the interest of the Provider to be certain that all information set for release omits all information related to privacy, trade secret, and competitive considerations.

7.13: Referral to the Office of the Attorney General

We urge the HPC remove the final sentence from Section 7.13 of the proposed regulations which reads: "The Commission may also refer a Final report to the Office of the Attorney General in other circumstances as appropriate." as it exceeds the statutory authority of the Commission.

In the statute the Legislature was clear in listing specific criteria which would prompt referral of a CMIR to the Attorney General. The statute however did not include language allowing the Commission the flexibility to refer cases to the Attorney General, "in other circumstances as appropriate." Inclusion of such provision in the proposed regulations is outside the scope of the statute and exceeds the power afforded the Commission.

Overall Timing of the CMIR Process: 7.05: Notice of Cost and Market Impact Review; 7.07: Information Requests to Providers and Provider Organizations; Timing; 7.11: Written Response by Provider or Provider Organization; Certification of Truth; 7.12 Final Report.

We ask the Commission to clarify the amount of time the 185-day timeframe may be extended for a CMIR by providing estimated timeframes and completion dates for delivery of both the HPC's preliminary and final reports.

M.G.L. c. 6D, §13 provides a 185-day timeframe for the completion of a CMIR while allowing the Commission to extend that timeframe if the Provider supplying information and documentation for the CMIR exceeds their required 21 days. However, the language in section 7.12 of the regulations only states that the Commission "may set a later date for the issuance of the Final Report." As such it is not explicitly clear if, for example, this means the Commission will add one day for each day beyond 21, one business day for each day beyond 21, or some other future date to be determined.

To help clarify this ambiguity we recommend the Commission in sections 7.05, 7.07, 7.11 and 7.12 provide an estimate to the subject of the CMIR of the expected timeframe for delivery of both the

preliminary and final reports (7.05) as well as updated timeframes following an organization's substantial completion of document production (7.07). We also ask the timeframe be updated following receipt of a provider's response to the Commission's preliminary report (7.11). In this way the HPC will provide more certainty to those parties involved in the proposed transaction, as well as other market participants and stakeholders, with respect to the overall duration of the process.

Additionally we would ask that in section 7.12 the Commission cite 7.07(2) along with 7.07(1) and 7.07(3) as it also relevant.

Thank you for your consideration of our comments and recommendations. We look forward to continuing to work with the Commission and HPC staff. Should you have any questions, please do not hesitate to contact me.

Sincerely,

John Erwin, Executive Director
Conference of Boston Teaching Hospitals