



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

MEMORANDUM

TO: Commissioner Monica Bharel, MD, MPH and Members of the Public Health Council

FROM: Jay Youmans, Senior Advisor to the Commissioner; Thomas Mangan, Policy Analyst; Nora Mann, Director, Determination of Need Program

CC: Rebecca Rodman, Senior Deputy General Counsel

RE: Final Proposed Revision of 105 CMR 100.000: Determination of Need

DATE: January 11, 2017

I. Introduction

The purpose of this memorandum is to request final approval for promulgation by the Public Health Council (PHC) of the proposed revision of Department of Public Health (DPH) regulation entitled *Determination of Need* found at 105 CMR 100.000.

A draft revision of 105 CMR 100.000 (“DoN regulation”) was brought before the PHC prior to its release for public comment on Tuesday, August 23, 2016. Following this initial presentation, the Department held two (2) public hearings in Boston, MA and Northampton, MA. DPH received and reviewed over 100 comments submitted at both the public hearings and during the corresponding 45 day comment period from a wide range of interested parties, from members of the General Court, local public health departments, community coalitions, and academics, to architectural and legal firms, public health advocates, health systems, physicians, and freestanding ambulatory surgery centers. Additionally, DPH held five (5) listening sessions across the state and invited written comments, in order to collect feedback on proposed sub-regulatory guidelines to be issued in support of the final proposed revision. In total, comments received through these seven (7) public hearings and three (3) public comment periods have informed the final proposed revision, summarized below and attached to this memorandum.

The proposed revision was also completed, in part, pursuant to the regulatory review process, mandated by Executive Order 562, which requires the Department of Public Health (DPH) and all other state agencies to review regulations with the goal of streamlining, simplifying, and improving said regulations. The final proposed revision represents a paradigm shift to a

modernized, streamlined, and retooled process that puts public health at the core of the Determination of Need (“DoN”) process.

II. Background

The mission of DPH is to prevent illness, injury, and premature death, to assure access to high-quality public health and health care services, and to promote wellness and health equity for all people within the Commonwealth. This mission has historically been understood to direct DPH to play an active role in 1) measuring population health and wellness, including the identification and understanding of the underlying social determinants of health, and 2) health care delivery system policy and design.

Consistent with this understanding, the Massachusetts General Court established the DoN Program within DPH in 1971. However, despite significant changes in health care over the past 45 years, the DoN regulation, with few exceptions, has remained substantively unchanged following its initial conception. As such, the Commonwealth’s current DoN regulation has been outpaced by a rapidly evolving health care market and is unable to successfully further DPH’s ability to incentivize value-based market competition that emphasizes successful implementation of population health strategies. (*See Attachment A*, August 23, 2016 DPH Staff Memo to PHC).

III. High-Level Overview

Following a comprehensive year-long review of the current DoN regulation, DPH released an initial proposed revision in August 2016. The proposed revision represents a paradigm shift from an antiquated, burdensome regulation to a modernized, streamlined, and retooled regulation that puts public health at its core.

To accomplish this, DPH staff proposed seven (7) major areas of revision:

- Simplification and predictability;
- Modernization and alignment across state agencies;
- Increased transparency;
- Accountability;
- Redirecting Community Health Initiative (CHI) projects towards the social determinants of health;
- Revamping of DPH oversight of DoN-Required Equipment and Services; and,
- Modernization of DPH’s review of transfers of ownership.

DPH’s initial proposed revision largely accomplished these goals by:

- Reducing the DoN regulation by 57%;
- Restructuring and reducing regulatory complexity, significantly streamlining the DoN application and review process for regulated parties;
- Modernizing DoN to reflect today’s health care market; looking across systems of care; retooling DoN to incentivize market competition based on value and the successful implementation of population health strategies, all in support of the public health mission;

- Ensuring increased access and equity by requiring MassHealth participation as a condition of DoN approval, and by creating a requirement that DoN projects must add demonstrable public health value and reasonable assurances of health equity to existing patients;
- Increasing transparency and predictability of DoN by allowing for a rolling application process, requiring real, meaningful, and continuous community engagement, requiring regular reporting and meaningful accountability by DoN holders;
- Reforming the state’s oversight of equipment and services to support high-value innovation, while limiting market saturation of equipment and services with evidence of having the potential for overutilization; and,
- Aligning terminology, processes, and policies across relevant state agencies, increasing state government’s ability to “speak with one voice” on important health care policy.

DPH’s final proposed revision maintains these tenets of reform, while responding to public comments received to-date.

IV. Summary of Public Comment and Proposed Department Amendments

Following DPH’s release of the initial proposed revision to 105 CMR 100.000, DPH held two (2) public hearings in Boston, MA and Northampton, MA and has received and reviewed over 100 comments submitted at both hearings and during the 45 day comment period from a wide array of constituencies. Additionally, DPH held five (5) listening sessions across the state and invited written comments on proposed sub-regulatory guidelines to be issued in support of the final proposed revision. Comments received across these seven (7) public hearings and three (3) public comment periods have informed the final proposed revision.

In summary, the majority of the feedback DPH received supported DPH’s overall approach to the DoN revision, with comments and suggestions for further amendments focused on several specific topic areas. The following topic areas represent the majority of all public comments received by the DPH.

- **Ambulatory Surgery:** A majority of the comments received in response to the initial proposed revision by DPH were on this topic. DPH’s goal in its initial proposed revision was to balance the needs of patients seeking greater access to ambulatory surgical services, with a thoughtful response to state and national data indicating increases in total medical spending, as well as increased fiscal insecurity for critical access community hospitals associated with the deregulation and expansion of ambulatory surgery centers or “ASCs”.¹ Specifically the proposed regulation sought to address the impact on community-based hospitals, as they represent important access points for many of the Commonwealth’s most vulnerable residents, by providing urgent, emergent, and primary services, regardless of payor.

¹For example, in Ohio there was a 600% increase in ASCs following their deregulation. Additionally, see recent HPC findings highlighting freestanding ASCs as one of several new market innovators contributing to the fiscal insecurity of the Commonwealth’s community hospitals.

While most commenters supported DPH's overall approach to the DoN revision, they objected to this specific section of the proposed revisions, citing that the ASC provisions failed to take into account the significant savings and quality benefits provided by independent freestanding ASCs. Atrius Health, the Massachusetts Medical Society, independent freestanding ASC operators, trade associations, and Massachusetts payors all provided testimony supporting this position. Beth Israel Deaconess Medical Center (BIDMC), the Conference of Boston Teaching Hospitals (COBTH), Lahey Health System, the Massachusetts Council of Community Hospitals (MCCH), the Massachusetts Health and Hospital Association (MHA), New England Baptist Hospital, Partners Health Care, Dr. Alan Sager (BU School of Public Health or "BUSPH"), Shields Health Care Group, Steward Health Care, UMass Memorial Health Care (UMMHC), and Wellforce all provided testimony in support of DPH's initial ASC proposal. MCCH noted through its oral testimony that while freestanding ASCs do in fact provide more affordable options for ambulatory surgical services, they are not required to take all patients, regardless of payor, their facilities have significantly lower-cost requirements, and they only provide higher-reimbursable services in comparison to many of the other necessary, lower-reimbursable services provided by community hospitals (e.g. primary and behavioral health services). Several ASC operators from western Massachusetts noted examples of community hospitals no longer providing hospital-based ambulatory surgical services and seeking freestanding ASCs to fill these gaps in service delivery within their communities. Atrius Health advocated for DPH to use ASCs as a way to incentivize and reward accountable care organizations (ACOs) seeking to take on greater downside risk, citing ACOs connection to actual patient need and value-based services. Dr. Paul Hattis (Tufts University School of Medicine or "TUSM") supported DPH's desired goals, but recommended that DPH redraft these provisions to provide some protection for community hospitals while also allowing for the continued growth of freestanding ASCs in order to encourage these lower-cost, freestanding settings.

The amendments proposed by DPH at this time are consistent with its desire to support community hospitals, incentivize the formation of value-driven and patient-centered ACOs, and acknowledge the important cost-saving contributions that the more than 50 existing freestanding ASCs within the Commonwealth have and continue to provide. As proposed, any Health Policy Commission (HPC) certified ACOs (ACOs which have been certified by the Division of Insurance as risk-bearing provider organizations and that have demonstrated to the HPC their ability to meaningfully involve consumers and begin to respond directly to the social determinants of health) can apply for proposed projects that include construction of freestanding ASC capacity (*Note: limited exemption for main campus and expansion of existing satellite campus capacity*), while grandfathering all existing freestanding ASCs, providing them the opportunity to expand at their existing sites or change ownership – activities prohibited under the current moratorium. Construction of a freestanding ASC at a new location must be done by an Applicant working either in joint venture with an HPC-certified ACO or by an existing independent community hospital. Additionally, should an HPC-certified ACO seek to locate a new

freestanding ASC location within the primary service area of one of the Commonwealth's 10 remaining independent community hospitals (i.e. independent, non-affiliated), the HPC-certified ACO would be required to either obtain a letter of support from the independent community hospital, or engage in a joint venture/affiliation with the independent community hospital. It should be noted that according to HPC's Massachusetts Hospital Cohort Designation and Affiliation Status, only 10 independent community hospitals are currently in operation, limiting this provision's scope, while still providing important protections for these valued and increasingly vulnerable community assets.

DPH's proposed amendments recognize the important contributions independent freestanding ASCs and community hospitals, both, have made in reducing the Commonwealth's total medical costs, while reflecting an understanding that the future of health care will rely on providers' abilities to better manage total costs and provide a whole health approach to patient care.

- **Transfer of Ownership:** The proposed regulation contemplates input from HPC in the context of transfers of ownership, specifically with respect to their Cost and Market Impact Reviews (CMIR). In this respect, DPH received conflicting comments: MHA requested that all references to HPC be struck. Conversely, Blue Cross Blue Shield of MA (BCBSMA), Harvard Pilgrim Health Care, Dr. Paul Hattis (TUSM), the Massachusetts Association of Health Plans (MAHP), the Massachusetts Nurses Association (MNA), Dr. Alan Sager (BUSPH), and UMMHC provided strong endorsements of DPH's proposed revision of the transfer of ownership process and its alignment with HPC. DPH received comments from COBTH and several of its members, including Lahey Health System and Partners Health Care, providing overall support for DPH's proposed revision of transfer of ownership provisions; however, sought additional clarity as to how DPH will consider comments made by HPC. Specifically, commenters asked for assurance that DPH would consider any HPC comments in the context of all applicable DoN Factors. Finally, Lahey, Partners, and BIDMC requested that DPH limit its consideration of any HPC comments submitted to DPH in response to a completed CMIR to only situations where the HPC refers a proposed project to the Massachusetts Attorney General.

Additional comments in response to this section spoke to the question of what kind of transaction would amount to a transfer of ownership for the purposes of the regulation. Specifically, representatives of some independent, physician-owned freestanding ASCs requested clarity around the "Transfer of Ownership" definition as it relates to limited liability partnerships and whether the retirement of one owner and the addition of another new owner would trigger the DoN transfer of ownership process.

In the final proposed revision before the Council, DPH has proposed amendments to clarify: that DPH will consider any comments submitted by HPC based upon a completed CMIR within the context of the applicable DoN Factors, and to define "Transfer of Ownership" to exclude certain limited changes to a partnership's

ownership structure, thereby aligning the DoN regulation with proposed definition changes within DPH's licensure regulations. DPH declines to further limit its ability to review transfers of ownership following an HPC review to only those for which an AGO referral has been made, as DPH believes transfers of ownership may warrant further DoN review, for rescission or amendment of the DoN approval, irrespective of a separate decision by HPC to refer a matter to the Massachusetts Attorney General. However, DPH did amend provisions to allow for due process to an applicant should DPH determine a rescission or further amendment to a previously issued DoN is warranted in response to received HPC comments.

- **Accountability:** BCBSMA, the Boston Public Health Commission (BPHC), Health Care for All, MAHP, House Majority Leader Ronald Mariano, MCCH, MNA, Dr. Alan Sager (BUSPH), and UMMHC all submitted comments supporting DPH's efforts to infuse transparency and accountability within DoN. While supportive, Dr. Sager believed that DPH did not go far enough. COBTH, while also supportive, requested that due process and consideration of external factors be included within the final revision. MHA believed the transparency and accountability measures were too burdensome and should be struck. DPH agrees that in some circumstances external factors should be considered and has proposed amendments to ensure appropriate process and has allowed applicants to request that certain external factors be considered in the context of compliance with conditions.
- **Proposed Project:** Partners Health Care asked whether the definition of a "Proposed Project" would allow for a Provider Organization to apply for DoN approval for an entire institutional master plan in a single application. DPH has proposed a clarifying amendment to this definition, as both the existing definition of a proposed project and DPH's initial proposed revision allow for "any combination" of projects, which would allow a Provider Organization to apply for DoN approval for an institutional master plan in a single application.
- **Disaggregation:** DPH received comments from MHA, Partners, and Steward requesting greater clarity regarding the definition and scope of "Disaggregation". Specifically, commenters requested that parameters, such as a prescribed timeframe or linkage to a facility's capital plan, be placed around the ban on disaggregation, adding greater predictability for regulated parties. Additionally, the MHA requested that the prohibition on disaggregation be limited to only clinical components of a proposed project, allowing for non-clinical projects to be disaggregated from their clinical counterparts.

Conversely, DPH received comments from MAHP and its member payors, as well as the Friends of Prouty Garden, a registered Ten Taxpayer Group, commending DPH's continued ban on disaggregation, stressing that this standard should not be weakened as it helps ensure critical transparency and accountability regarding providers' capital expenses – clinical and non-clinical – as they relate to the Commonwealth's Total Health Care Expenditure.

DPH staff believe that maintaining the ongoing practice of prohibiting disaggregation gets at the heart of the DoN process, and therefore, consistent with statute, should not be limited to clinical components only. While a specified timeframe could provide additional predictability both for regulated parties and DPH, this approach does not fully reflect that more complex capital projects may result in reasonably related expenses across a multi-year period. Additionally, linking the prohibition on disaggregation to a specific health care facility's capital plans fails to reflect that the applicant under the proposed DoN regulation is the entire system. The prohibition on disaggregation allows DPH to look across systems of care, which is appropriate as Provider Organizations increasingly contemplate capital expenditures across multiple facilities and campuses, all of which are reasonably related and tied to an applicant's vision for providing health care services to its patient panel. As such, DPH strongly recommends retaining its discretion with regards to the prohibition on disaggregation.

However, DPH does recommend amendments, at this time, to clarify that – for the purposes of Conservation Projects – the ban on disaggregation is limited to only projects within the same health care facility. This approach reflects the reality that an applicant may seek a Conservation Project at one health care facility, while pursuing a significant upgrade or addition at a separate health care facility. As proposed, DPH has delineated a systems view for expansions beyond current capacities, but a facilities-based view for Conservation Projects that simply look to maintain current capacities.

- **Conservation Projects:** DPH received comments from BIDMC, COBTH, the Massachusetts Business Roundtable, MCCH, MHA, Partners, Steffian Bradley Architects, and Wellforce commending DPH on its inclusion of Conservation Projects. Commenters generally sought clarity on the scope of Conservation Projects, specifically as the definition relates to nationally recognized facility guidelines and whether such recommended and recognized best-practices would be eligible as Conservation Projects. DPH has clarified that these provisions allow for proposed projects that – without disaggregation within a health care facility – seek to conform to such nationally recognized standards, such as the Facility Guidelines Institute, the Joint Commission, and the America Institute of Architects.
- **Community Health Initiative (CHI) Projects:** BCBSMA, BIDMC, BPHC, Elmer Freeman (Northeastern University), Enid Eckstein, Dr. Paul Hattis (TUSM), Harvard Pilgrim Health Care, Health Care for All, MAHP, MCCH, the Massachusetts Public Health Association (MPHA), Steward, and UMMHC all submitted comments supporting DPH's CHI revision. Conversely, MHA requested that CHI requirements be struck and that DPH allow for hospitals to direct any CHI dollars to projects they select. Separately, Massachusetts Senior Care and LeadingAge Massachusetts both expressed concerns with DPH's proposed expansion of CHI included long-term care providers, citing nursing home viability and current rates. Both organizations requested that DPH consider financial sustainability triggers or updated CHI thresholds specific to long-term care. As DPH maintains that access alone is not sufficient to tackle health care costs, DPH's final proposed revision maintain the

proposed expansion of CHI; however, DPH has proposed that long-term care projects provide funding greater than or equal to 3% (down from 5%) for all proposed projects other than Conservation Projects, and 1% (down from 2.5%) for all Conservation Projects. This approach maintains DPH's prioritization of CHI as a critical component of DoN, while responding to the long-term care industry's concerns.

- **Provider Organization:** BCBSMA, MAHP, Partners, and Steward commended DPH for its efforts to look across systems of care, reflecting the modern health care market. BIDMC, also generally supportive, recommended that DPH consider amending this definition to ensure entities like BIDMC and other hospital systems which may not have a parent entity directly contracting with payors continue to apply as individual hospital facilities. DPH's final proposed revision simplifies the definition of "Provider Organization" in order to ensure that the highest corporate entity, regardless of whether they contract directly with payors, is both the applicant and DoN holder.
- **Health Priorities:** COBTH, Lowell General, Partners, and MHA provided comments on DPH's proposed definition of Health Priorities, requesting DPH provide clarity around who would establish such priorities and to ensure that ongoing community health needs assessments would be reviewed and inform DoN Health Priorities development. DPH's proposed final revision responds to these comments by clarifying that DPH will develop DoN Health Priorities in consultation with providers, stakeholders, sister state agencies, and the PHC, and that community health needs assessments would be reviewed and considered in the context of DPH's establishment of said Health Priorities.
- **Price:** BCBSMA and Partners both encouraged DPH to look beyond incentivizing competition solely on the basis of "price", but to also look at Total Medical Expenditure (TME), provider costs, and other recognized measures of cost. DPH maintains that competition on the basis of value, inclusive of price, is critical to ensuring increased outcomes and decreased costs. To this end, DPH has maintained "price" as a component part of "value"; however, consistent with these comments, DPH has proposed amendments making explicit its intent to look at a Proposed Project's potential impacts on TME and other recognized measures of cost.
- **Independent Cost Analysis:** Dr. Paul Hattis (TUSM) commented regarding the independent cost analysis (ICA). Specifically, Dr. Hattis encouraged amendments to ensure any such required analyses are truly "independent" by clarifying the client-vendor relationship and the role of the applicant. Additionally, Dr. Hattis encouraged greater collaboration between DPH, HPC, and other relevant state agencies. Additionally, COBTH requested greater clarity regarding timelines associated with the ICA process, specifically when DPH can require such an analysis and the timeframe in which parties of record may respond. DPH has proposed amendments relative to a required ICA, establishing that DPH will craft all questions on which an analysis would be conducted, completed by a mutually agreed upon vendor. Once selected, the applicant's role is limited to responding to questions posed by the vendor

in connection with its analysis. DPH also clarifies the process by which parties of record, including the HPC, AGO, and other relevant state agencies may review and comment on the ICA. The ICA will not be completed until such time the Commissioner “accepts” the ICA and deems it complete; however, DPH must request an ICA within 30-days of receiving a completed DoN application.

- **Patient Panel:** Steward strongly supported DPH’s proposed definition of “Patient Panel”, but requested that the definition be clarified to ensure consideration was inclusive of all patients regardless of payor. COBTH and MHA requested that the definition be restricted to all patients seen within the most recently completed 12-month period (down from DPH’s initially proposed 36 months). State Senator John F. Keenan provided comment requesting that DPH clarify the definition to include all patients seen through an applicant’s emergency department, if applicable. DPH maintains its recommendation that patient panel be defined as all patients seen by an applicant within the most recently completed 36-month period, aligning with HPC’s existing definition of patient panel. Additionally, DPH concurs with Senator Keenan and Steward’s proposed clarifications, and has proposed changes accordingly.
- **Medicaid Participation Standard Condition:** BCBSMA, BIDMC, BPHC, Dr. Paul Hattis (TUSM), Health Care for All, Lowell General Hospital, MAHP, MCCH, Partners, Dr. Alan Sager (BUSPH), and Steward all provided comments strongly supporting this proposed provision. MHA shared concerns regarding DPH-proposed Standard Condition requiring Medicaid participation by all DoN holders. It is DPH’s position that the goal of the DoN program – a voluntary program – as set out in its authorizing statute, is to ensure access to health care services for all residents of Massachusetts. Therefore, DPH retains its requirement that all eligible DoN holders demonstrate participation in, or their intent to participate in, Medicaid as a Standard Condition of DoN approval.
- **CLAS and Language Access Standard Conditions:** Dr. Monika Mitra of the Lurie Institute for Disability Policy (Brandeis University) provided comments to DPH requesting that DPH memorialize current language access conditions typically attached by the Public Health Council and DPH’s Office of Health Equity (OHE) as Standard Conditions within 105 CMR 100.000. DPH agrees that these critical OHE conditions should be added as Standard Conditions, as well as current CLAS facilities licensure standards. Three such Standard Conditions have been incorporated within the final proposed revision.
- **Factor 4/CPA Analysis:** Atrius Health, LeadingAge MA, and MHA expressed concerns that DPH’s proposed CPA financial analysis within Factor 4, calling it burdensome and unnecessary. Additionally, commenters expressed concerns that such a requirement may open up confidential proprietary information to public release. Hospitals requested that DPH provide legal protections for this information, similar to that provided by HPC for its Cost and Market Impact reviews.² While concurring

²Note: HPC’s authorizing statute provides specific protections of submitted information. Similar protections are not currently provided to DoN by way of its enabling statute.

with confidentiality concerns, Steward strongly supported the inclusion of an independent CPA's analysis, and further provided recommendations that DPH require a 5-year sustainability analysis to ensure that any proposed project has financial viability beyond its initial build-out. DPH notes that 1) all of the information required within Factor 4 is within the scope of the current DoN regulation's analysis of an applicant's finances; and 2) unlike the current DoN application process, the financial information itself will not be provided to DPH; rather, the independent CPA will review the applicant's information and, following such review, will provide the necessary assurance that the applicant has the financial means to support the Proposed Project. With respect to the 5-year sustainability analysis, DPH has proposed an amendment to Factor 4 to reflect this recommendation.

- **Emergency Applications:** MHA and several of its members provided comments regarding emergency applications, specifically regarding timing, the role of the Commissioner in establishing an emergency situation, and the continued requirement to fund Community Health Initiatives. MHA and its members stated that if an emergency situation existed pursuant to a government-established emergency, the Commissioner should not be required to first establish if an emergency situation in fact exists. In a reflection of the importance of an expedient, comprehensive response to an emergency situation, DPH has updated these provisions, further streamlining and clarifying the emergency definition and process, while removing the CHI requirement.
- **Accountable Care Organizations:** DPH received comments from Atrius Health and Steward Health Care encouraging DPH to consider ways in which to reward and incentivize greater adoption of value-driven and patient-centered ACOs. DPH has proposed such incentives through its contemplation of ASCs and delegated review.
- **Acute Care Hospital:** MHA and several of its members provided comment citing recent changes pursuant to Chapter 420 of the Acts of 2014, providing consistent application of DoN across all "Hospitals" as a provider class. DPH has amended the proposed final revision to not differentiate between acute and non-acute hospitals.
- **Effective Date, Sub-Regulatory Guidance, and Grandfathering:** Massachusetts Senior Care submitted comments seeking clarity on the effective date of the final revisions, in particular, any impact upon currently pending applications or previously approved DoNs. They also sought clarification regarding existing DoN sub-regulatory guidelines. DPH has put forward no amendments in response to these comments; however, the final proposed revision, once promulgated, would have no impacts on currently pending applications or previously issued DoNs – only DoN applications received following the revision's date of promulgation. With respect to existing sub-regulatory guidelines, concurrent with the submission of these revised regulations, DPH staff will propose and seek the PHC's support on certain updated guidelines related to Health Priorities/CHI, Public Health Value, DoN-Required Equipment and Services, and the repeal of a number of previously issued and obsolete sub-regulatory guidelines.

V. Conclusion

In conclusion, DPH's final proposed revision is informed by a comprehensive year-long review, robust public engagement involving seven (7) public hearings across the state and three (3) public comment periods, as well as over 100 stakeholder and expert meetings and interviews. DPH staff request that Public Health Council vote to approve these regulations for final promulgation, firmly establishing public health at the core of the DoN process, and setting a new national standard for certification of need oversight.