



# Commonwealth of Massachusetts Department of Public Health

## *Final Proposed Revision of Determination of Need, 105 CMR 100.000*

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January 11, 2017



## Presentation Overview

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- Background**
- Overview of Public Comment and Proposed Further Revisions**
- Summary, Next Steps, and Timeline**
- Questions**



## Background

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- Following a **comprehensive year-long review**, in August 2016, DPH presented to the PHC and publicly released a proposed revision to the DoN Regulation.
- This revision marked the **first top-to-bottom review and revision** of the DoN Regulation since its inception in 1971.
  - ❑ **1971:** DoN established.
    - ✓ **Providers:** Care largely provided in standalone, not-for-profit hospitals or small group practices.
    - ✓ **Payment:** Fee-for-service or cost-based reimbursement. Rate setting commission set public rates.
    - ✓ **DoN:** Played a critical role in protecting MA from state overspending on new technologies and duplicative services. Goal was to prevent saturation through non-duplication of services.
  - ❑ **2016:** Post-Chapter 224 and federal health reform.
    - ✓ **Providers:** Significant provider consolidation. Complex health systems that closely control patient referral patterns. Increased reliance on innovation through technologies and services.
    - ✓ **Payment:** Systems taking on increased risk and no government rate setting.
    - ✓ **DoN:** Objective has been the non-duplication of services, rather than incentivizing competition on basis of value. Increasingly out of alignment with DPH mission (*i.e.* population health) and state goals for delivery system transformation.



## Background

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- DPH's revision **represents a paradigm shift** to a modernized regulation that puts public health at its core.
- **Seven (7) major areas of revision:**
  1. Simplify and Streamline
  2. Modernize to Reflect the Modern Health Care Market and Realign with DPH Core Mission
  3. Increase Objectivity and Transparency
  4. Create True Benchmarking and Accountability of DoN Projects
  5. Leverage CHI Investments Towards State Health Priorities
  6. Reframe Reviews to Non-Innovative Equipment and Technologies
  7. Align Incentives with Community Hospital Sustainability



## Background

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DPH's initial proposed revision accomplished these goals by:

- **Reducing the DoN regulation by 57%**, significantly reducing regulatory complexity;
- **Restructuring and streamlining** the DoN application and review process;
- Modernizing DoN to reflect today's health care market by **looking across systems of care and incentivizing value-based market competition** and the successful implementation of population health strategies;
- Ensuring equitable access by **requiring MassHealth participation** and reasonable assurances of health equity;
- **Increasing transparency, predictability, and accountability** with a rolling application process, meaningful community engagement requirements, and regular reporting by DoN Holders;
- Refocusing oversight of equipment and services those with **evidence of overutilization**; and
- **Aligning terminology, processes, and policies across relevant state agencies.**



## Background

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- Initial PHC presentation on August 23, 2016
- **Two public hearings** in Boston, MA and Northampton, MA and an extended public comment period
- DPH received and reviewed **more than 100 comments** from a wide range of interested parties
- **Five listening sessions across the state** and two comment periods dedicated to proposed sub-regulatory guidelines
  - DPH's stakeholder engagement was recently cited by the Public Health Accreditation Board (PHAB) as a model example during DPH accreditation review
- Comments received through these **hearings, listening sessions, and comment periods informed the final proposed revision**



## Summary of Comments

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- **The majority of public comment strongly supported DPH's overall approach**
- Most comments and suggestions for further amendments focused on several specific topic areas:
  - Ambulatory Surgery
  - Transfer of Ownership
  - Accountability
  - Disaggregation
  - Conservation Projects
  - Community Health Initiative (CHI) Projects
  - Provider Organization
  - Independent Cost Analysis
  - Patient Panel
  - Medicaid Participation Standard Condition
  - CLAS and Language Access Standard Conditions



## Ambulatory Surgery

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### Initial Draft Regulation:

- Goal: to balance the needs of patients seeking greater access to quality, low cost ambulatory surgery with a thoughtful response to increased fiscal insecurity for community hospitals associated with growth in freestanding ASCs
- The majority of the comments received in response to the initial proposed revision focused on this topic

### Summary of Comments:

- Hospitals strongly supported initial proposal
  - Community hospitals noted that while freestanding ASCs provide more affordable ambulatory surgery, they are not required to treat all patients, and do not provide many of the critical lower-reimbursement services provided by Community hospitals (e.g. primary and behavioral health services).
  - Freestanding ASCs and payers strongly objected to this provision, citing significant savings and comparable quality provided by independent freestanding ASCs
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## Ambulatory Surgery

### Initial Draft:

- Careful lifting of the current ambulatory surgery moratorium.
- No Notice of Determination of Need to be issued unless the proposed ambulatory surgery project is:
  1. Applied for by an existing hospital either on main campus or as a freestanding ASC off main campus; or,
  2. Constitutes a joint venture with an existing hospital.
- Reiterates that if a proposed freestanding ASC project would be located in a competitor hospital's primary service area (PSA), the proposed project must compete on the basis of price and respond to existing patient panel need(s).

### Proposed Amendment(s):

- Careful lifting of the current ambulatory surgery moratorium.
- Grandfathers existing freestanding ASCs - allowing them to expand, convert, sell, or transfer their site (but not to build new sites without becoming a joint venture with an HPC-certified ACO).
- Allows HPC-Certified ACOs to:
  - Build additional ambulatory surgery capacity on a main campus;
  - Expand or convert existing ambulatory surgery capacity at a satellite campus;
  - Build a new freestanding ASC;
  - Enter into a joint venture to build a new freestanding ASC.
- For projects located in the primary service area of an independent community hospital, requires a letter of support or a joint venture arrangement.



## Transfers of Ownership

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### Initial Draft Regulation:

- Realigns review of mergers and acquisitions with DPH's mission; requires evidence of measurable public health value; leverages HPC's Cost and Market Impact Reviews (CMIR).

### Summary of Comments:

- Blue Cross Blue Shield (BCBSMA), Harvard Pilgrim Health Care, Dr. Paul Hattis (TUSM), the Massachusetts Association of Health Plans (MAHP), the Massachusetts Nurses Association (MNA), and UMass Memorial Health Care (UMMHC) strongly supported DoN's alignment with HPC.
- Lahey and Partners requested that DPH clarify the process and scope of its consideration of any comments received by HPC in connection with its CMIR.
- Lahey, Partners, and BIDMC supported the alignment and revamped process, but requested that DPH limit its consideration of HPC comments to situations where the HPC refers a proposed project to the Massachusetts Attorney General.
- Freestanding ASCs requested increased clarity on the definition of "Transfer of Ownership".



## Transfers of Ownership

### Initial Draft:

- ❑ Streamlined process; requires evidence that project would add measurable public health value; leverages HPC's CMIR.
- ❑ For applicants subject to a CMIR, establishes that a Notice of Determination of Need shall not go into effect until such time the HPC has completed its CMIR.
- ❑ Allows the Commissioner to rescind the Notice of Determination of Need on the basis of HPC's CMIR findings.
- ❑ No "Transfer of Ownership" definition.

### Proposed Amendment(s):

- ❑ Maintains streamlined and reframed process and effective date tied to completion of HPC's CMIR.
- ❑ Clarifies that DPH will consider comments submitted by HPC only within context of applicable DoN Factors.
- ❑ Clarifies process for applicant response to a rescission or request for amendment based on HPC comments.
- ❑ Adds a definition of "Transfer of Ownership", aligning the DoN regulation with DPH licensure regulations.



## Accountability

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### Initial Draft Regulation:

- Requires regular post-approval reporting.
- Allows PHC to require holders to contribute additional Community Health Initiative (CHI) resources if they fail to meet the promises and/or measures they attested to during the DoN approval process.
- Conditions the facility licenses with all terms and conditions of the DoN approval.

### Summary of Comments:

- BCBSMA, the Boston Public Health Commission (BPHC), Health Care for All, MAHP, House Majority Leader Ronald Mariano, MCCH, MNA, and UMMHC strongly supported DPH's efforts to infuse transparency and accountability within DoN.
- Dr. Alan Sager (BUSPH) strongly supported these measures, but believed DPH should go further.
- COBTH, while generally supportive, requested process clarification and consideration of external factors be included within the final revision.

### Proposed Amendment(s):

- Clarifies process and that PHC has the discretion to consider external factors in holder compliance.
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## Disaggregation

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### Initial Draft Regulation:

- Incorporates into regulation existing ban on disaggregation of reasonably related projects.

### Summary of Comments:

- MHA, Partners, and Steward requested greater clarity regarding the definition and scope of “Disaggregation”; specifically, the addition of clarifying parameters, such as a prescribed timeframe or linkage to a facility’s capital plan.
- MHA requested that the prohibition on disaggregation be limited to only clinical expenditures of a proposed project.
- MAHP and its member payors, as well as the Friends of Prouty Garden, a registered Ten Taxpayer Group, stressed that banning disaggregation should not be weakened.

### Proposed Amendment(s):

- Prohibition on disaggregation is at the heart of the DoN process, and therefore, consistent with statute, should not be limited to clinical expenditures only.
  - Clarifies that for Conservation Projects, disaggregation refers only to projects at the same health care facility (rather than provider organization).
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## Conservation Projects

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### Initial Draft Regulation:

- Creates an expedited review process for restoration or “Conservation Projects” that meet the expenditure minimum, but – in their entirety and without disaggregation – simply maintain a building or service for its designated purpose and original functionality without modernization, addition, or expansion (e.g. new roof, painting, carpeting, electric, catch up on deferred maintenance), creating a significant regulatory simplification.

### Summary of Comments:

- BIDMC, COBTH, the Massachusetts Business Roundtable, MCCH, MHA, Partners, Steffian Bradley Architects, and Wellforce commended 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.

### Proposed Amendment(s):

- 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.
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## Community Health Initiatives (CHI)

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### Initial Draft Regulation:

- Aligns Community Health Initiatives (CHI) with DoN “Health Priorities”, supporting evidenced-based, population health projects and providers’ in efforts to successfully assume increased risk.
- Focuses on changing the conditions within communities by tackling the underlying social determinants that drive health and disease – and therefore, costs.

### Summary of Comments:

- 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 submitted comments supporting this approach.
- Massachusetts Senior Care and LeadingAge Massachusetts expressed concerns with including long-term care providers, citing nursing home viability and current rates.

### Proposed Amendment(s):

- DPH maintains the proposed expansion of CHI, with limited adjustment to contributions required for Long Term Care Applicants.
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## Provider Organization Definition

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### Initial Draft Regulation:

- Leverages HPC's definition of "Provider Organization" for the purposes of Material Change regulations and cost trend reporting.

### Summary of Comments:

- BCBSMA, MAHP, Partners, and Steward strongly support 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 payers continue to apply as individual hospital facilities.

### Proposed Amendment(s):

- DPH agrees with BIDMC that the initial draft's definition of "Provider Organization" created unintended operational complications, as many hospital "parent" organizations do not directly contract with commercial insurers.
  - A simplified definition of "Provider Organization" to ensure that the highest corporate entity, regardless of whether they contract directly with payers, is both the applicant and DoN holder.
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## Patient Panel

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### Initial Draft Regulation:

- Requires that Applicant demonstrate need for Proposed Project by applicant's existing "Patient Panel" (all patients seen by the applicant within the past 36 months).

### Summary of Comments:

- 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 payer.
- COBTH and MHA requested that the definition be restricted to all patients seen within the most recently completed 12-month period.
- 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.

### Proposed Amendment(s):

- DPH maintains its recommendation for 36-month period, ensuring alignment with HPC.
  - Recommends amendment to clarify that patient panel should include all patients, regardless of payer, and all patients seen through an applicant's emergency department(s), if applicable.
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## Medicaid Participation

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### Initial Draft Regulation:

- Includes a Standard Condition, requiring that all eligible Holders demonstrate participation in, or their intent to participate in, MassHealth, advancing the Administration's efforts to realign state Medicaid spending with ACO advancement.

### Summary of Comments:

- 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 requiring Medicaid participation by all DoN holders.

### Proposed Amendment(s):

- DPH maintains 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 recommends retaining this requirement.
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## CLAS and Language Access

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### Initial Draft Regulation:

- Not specified within the initial draft regulation (but have been included operationally as conditions of past approvals).

### Summary of Comments:

- Dr. Monika Mitra of the Lurie Institute for Disability Policy (Brandeis University) requested that DPH memorialize currently operationalized language access conditions typically attached by the Office of Health Equity (OHE) as Standard Conditions within the final proposed revision.

### Proposed Amendment(s):

- DPH agrees that these critical OHE conditions should be added as Standard Conditions, reinforce current hospital and clinic facilities licensure standards.



## Summary

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DPH's final proposed revision is informed by a comprehensive year-long review and robust public engagement involving eight (8) statewide public meetings, several opportunities for public comment on the regulations and the accompanying guidelines, and over 200 meetings and interviews with stakeholders and content experts.

The proposed final revision:

- ❑ **Significantly streamlines and simplifies the DoN regulation**, reduces administrative burden, makes common-sense reforms, and enhances cross-agency collaboration and coordination;
- ❑ **Modernizes DoN** to reflect today's health care market by incentivizing value-based, population health-driven competition;
- ❑ **Increases transparency and objectivity** by insisting on real community engagement;
- ❑ **Adds true accountability** by requiring post-approval reporting on public promises made by DoN applicants;
- ❑ **Aligns community investments with actual data-driven needs**;
- ❑ **Levels the playing field**, supporting critical community assets;
- ❑ **Meaningfully infuses public health into DoN** by supporting providers as they assume additional risk and aligning with the Commonwealth's health care delivery system transformation goals.



## Next Steps and Timeline

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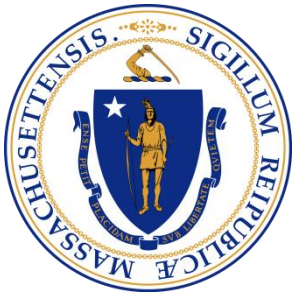
- DPH staff request that Public Health Council vote to approve these regulations for final promulgation.
- Promulgation of DPH's final proposed revision will firmly establish public health at the core of the DoN process, and set a new national standard for certification of need oversight.

## Regulation Timeline

- Wednesday, January 11, 2017:** DPH Staff Request PHC Vote
- Friday, January 13, 2017:** Revised Regulation Filed with the Secretary of State
- Friday, January 27, 2017:** Revised Regulation Goes Into Effect\*\*

**\*\*Note:** DPH's final revision, once promulgated, will have no impact on currently pending applications or previously issued DoNs – only DoN applications received following the revision's date of promulgation.

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# Commonwealth of Massachusetts Department of Public Health

*Proposed Revision of the Determination of  
Need Regulation 105 CMR 100.000*

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*Questions?*