Maura T. Healey
Governor

Kimberley Driscoll
Lieutenant Governor

Kiame Mahaniah, MD, MBA
Secretary

Robert Goldstein, MD, PhD
Commissioner

Determination of Need Application Instructions

July 2025



Massachusetts Department of Public Health

Dear Applicant:

On January 11, 2017, the Massachusetts Public Health Council (PHC) approved a significant revision of the Determination of Need ("DoN") Regulation ("Regulation"). Promulgated pursuant to M.G.L. c.111,§§ 25B to 25G, §§ 51 through 53, 51A, and 71, the goal of DoN and the framework for analysis by the Department of Public Health (DPH or Department) is to promote population health and increased public health value in terms of improved health outcomes, increased quality of life, and increased access to care. In so doing, the Department hopes to incentivize competition with a public health focus, and to support the development of innovative health delivery methods and population health strategies.

Applicants must provide sufficient evidence that a Proposed Project, on balance, is superior to alternative and substitute methods for meeting existing patient panel needs, including alternative evidence-based strategies and public health interventions. Applicants must make a clear and convincing demonstration that the Proposed Project meets each of the applicable Determination of Need Factors.

As of this date, the Application Form (Form) is in several parts. On this website, you will find a fillable form which must be used by all Applicants. In addition, there are supplemental forms1a which must be filled out and submitted. We provide them separately to accommodate the size of the document and also in the event that there are different people filling out different portions of the required information. In the pages that follow, you will find the Instructions. Applicants are encouraged to check this website regularly and, in any event, before preparing and filing an Application.

The Form, in its entirety, must be completed for all Applications for DoN. The Form is provided as a guide and may be modified from time to time to reflect changes in the DoN review process. The Form will become a part of the record through which the Applicant is required to make a clear and convincing demonstration that the Proposed Project meets all applicable DoN Factors.

The Department may publish Sub-regulatory Guidelines that will inform the DoN process. Applicants are advised to review any and all Guidelines in the context of preparing their application.

Please read the instructions and the Form thoroughly before you start an Application. Applications that are incomplete shall not be accepted. If you have questions, please contact the DoN Program staff at 617-624-5690 or dph.don@state.ma.us

Sincerely,
Dennis Renaud,
Director, DoN Program

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Purpose of DoN

The purpose and objective of the DoN program and the regulations thereunder is to encourage competition and the development of innovative health delivery methods and population health strategies within the health care delivery system to ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost, improving the health outcomes of the public, and advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

Content of Application

Applications for Determination of Need for any Proposed Project shall include, at a minimum:

1. Application - Fillable form
    a. List of Affiliated Parties Table
    b. Change In Service Chart
2. Filing fee (mail check, as applicable);
3. Documentation per checklist including, as relevant:
    a. Copy of Notice of Intent
    b. Affidavit of Truthfulness Form
    c. Certification from an independent Certified Public Accountant
    d. Notification of Material Change
    e. Articles of Organization/Trust Agreement/Partnership Agreement, etc.
    f. Link to Current IRS Form, 990 Schedule H CHNA/CHIP and/or Current CHNA/CHIP submitted to Massachusetts AGO's Office
    g. Community Engagement Plan form
    h. Community Engagement Stakeholder Assessment form
    i. Community Engagement-Self Assessment form14

Please use the Documentation Checklist at the end of the Application to determine, based upon the type of Application, whether there are any specific and/or additional requirements. Whether the Application is "complete" as that term is used in the Regulation will be determined by Staff. The Submission Date will be determined based upon the date that the Application is deemed substantially complete by the DoN Staff.

Before you File

Before submitting, any Applicant should have contacted the Department's Office of Health Equity (OHE) and the Community Health staff.

OHE – Make sure that you have reviewed and understand Standard Conditions 100.310(N)-(P) which require an understanding of culturally and linguistically appropriate services (CLAS) and require that any Holder provide a plan.

Community Engagement – For compliance with Factor 1, Applicants need to have considered the community engagement required and, depending upon the size of the project and which Tier they fall under, may have had to submit a Community Engagement Plan prior to the filing of the Application.

Filing the Application

All materials, and any other information that the Applicant wishes to be put before the Department in its review will be accepted by e-mail (dph.don@state.ma.us) only – do not submit hard copies. An electronic copy of the Application shall be submitted, simultaneously, to the AGO, CHIA, HPC, and to all Government Agencies with relevant licensure, certification, or other regulatory oversight[1] of the Applicant or the Proposed Project, or components therein. Any attachments required by the Application must also be submitted electronically. Any additional charts must be submitted in native file format.

[1] To the extent that this Applicant is subject to municipal zoning, it is not a requirement that the entire Application be submitted to the relevant permit granting authority. Rather, this requirement contemplates achieving sufficient transparency that relevant stakeholders in any municipality which will be affected by the Proposed Project are reasonably likely to be made aware of the pendency of the DoN filing.

Filing Fee

The filing fee shall be nonrefundable and shall be $500 or 0.2% of the Total Value of the Proposed Project, whichever is greater.

Applicant must send a check or money order made payable to the "Commonwealth of Massachusetts" in the amount of the filing fee indicated above.

Please include a scan of the check with this Application when it is filed electronically.

Publication and Notice

All Persons seeking a Notice of Determination of Need, or an amendment to a previously issued Notice of Determination of Need, shall publish notice thereof ("Notice of Intent") at least 14 days prior to the Submission Date of such Application or amendment with the Department. Please see the regulation, 105 CMR 100.405(C) for content and manner of publication.

At the time of publication, the Applicant shall also provide an electronic copy of the Notice of Intent to the Department, all Parties of Record, and all carriers or third-party administrators for the payment of health care services, including Medicare and Medicaid, with which the Applicant contracts. Any errors identified by the Commissioner shall require republication.

Calculation of Time

Time as used within the Determination of Need Process, includes every calendar day, whether the Department is open for business on that day or not, except that, when the last day of a specified period of time falls on a day when the Department is closed for business, such period shall end, instead, on the next day on which the Department is open for business.

Application Number

An application number will be generated at the time of filing. Please be sure to put that number on any and all correspondence with the Department.

Application Checklist Matrix

	Original License	Substantial Expend/ change (all but LTC/FASC)	LTC Substantial Expend/change	Freestanding ASC 105CMR 100.740(A)(1)(a)(iii)	Conservation/ Hospital	Conservation /LTC	Transfer of Ownership	Transfer of Site	DoN Required Service or Equipment	Amendments		
										Immaterial	Minor	Substantial
Cover Sheet	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Affidavit	✓	✓	✓	✓	✓	✓	✓		✓			
Statement of Beds/Services	✓	✓	✓	✓	✓	✓	✓		✓			
Matrix of Affiliated Parties	✓	✓	✓	✓	✓	✓	✓		✓			
Factor 1	✓	✓	✓	✓			✓	✓	✓			
Factor 2	✓	✓	✓	✓			✓	✓	✓			
Factor 3	✓	✓	✓	✓	✓	✓	✓	✓	✓			
Factor 4	✓	✓	✓	✓	✓	✓	✓	✓	✓			
Factor 5	✓	✓	✓	✓					✓			
Factor 6	5%	5%	3%	5%	2.5%	1%	Exempt		5%			
Evidence that Applicant is Certified ACO				✓								
Other Requirements				Joint Venture with Hosp. or Letter of support 105CMR 100.740(A)(1)(b)(i), or (ii) (attached)				Notice 105 CMR 100.745	See Guideline			
				Grandfathered 105CMR 100.740(A)(1)(a)(iv)								

Please use these Instructions and Definitions when responding to the questions in the Application Form, specifically those questions addressing the requirements of 105 CMR 100.210

Factor (1) Applicant Patient Panel Need, Public Health Value, and Operational Objectives

Patient Panel means the total of the individual patients, regardless of payer, including those patients seen within an emergency department(s) if applicable, seen over the course of the most recent complete 36-month period by the Applicant. When asked to describe your existing Patient Panel, please include incidence or prevalence of disease or behavioral risk factors, acuity mix, noted health disparities, geographic breakdown expressed in zip codes or other appropriate measure, demographics including age, gender and sexual identity, race, ethnicity, socioeconomic status and other priority populations relevant to the Applicant's existing patient panel and payer mix.

To fulfill this requirement successfully, you must provide supporting data to demonstrate the need for the Proposed Project. Looking at the Patient Panel, provide data that demonstrates the disease burden, behavioral risk factors, acuity mix, health disparities, or other objective Patient Panel measures as noted in your response to Question 1(a)(i) that demonstrates the need that the Proposed Project is attempting to address. If the Proposed Project is not directed at addressing an inequity or disparity, you must describe the other justifications of the need. Note that for the purposes of Factor 5, you will be asked to address each of those established needs in the context of the Relative Merit of the proposal as it addresses those needs. Applicants will be well-served to consider the principles underlying Public Health Value (more information below) and ensure that Need is addressed in that context as well. Following a description of the patient panel and its needs, please address Competition. That is, provide evidence that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending.

Question 1(b) Public Health Value – Applicants must demonstrate Public Health Value of the Proposed Project by showing that it will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity. For the purposes of this Factor 1, Public Health Value should be measured with reference to the Patient Need articulated in response to Question 1(a), above.

Public Health Value –
This information is provided to guide the Applicant in the context of demonstrating the Public Health Value of the Proposed Project.

The enforcement of the DoN Regulation is guided by an analysis of whether a Proposed Project will result in improved health outcomes for its patients. To that end, the DoN Regulation requires that any Applicant demonstrate that the Proposed Project will add measurable Public Health Value in terms of improved health outcomes and quality of life of the Applicant's existing Patient Panel (See 105 CMR 100.210(A)(1)(b)).

The concept of Public Health Value is based on healthcare based measures of quality; defined by the Institute of Medicine (IOM) as, "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."

Public Health Value, for the purposes of DoN, builds on IOM's definition and other nationally recognized quality measures such as those described by the National Quality Measures Clearinghouse, establishing a framework comprised of four (4) groupings of questions that the Applicant is required to respond to as part of a completed Application.

Need-Based: Provide data to demonstrate the need for the Proposed Project. Such data should demonstrate the disease burden within the existing Patient Panel (e.g., incidence or prevalence of disease or behavioral risk factors), the presence of a health disparity or inequity within the Patient Panel, or another objective measure that demonstrates the need that the Proposed Project will address.
Evidence-Based: Please provide information on the evidence-base for the Proposed Project. That is, how does the Proposed Project address the Need-Base (*See* above, Item 1).
Outcome-Oriented: Describe the impact of the Proposed Project and how the Applicant will assess such impact. Provide projections demonstrating how the Proposed Project will improve health outcomes, quality of life, or health equity. Only measures that can be tracked and reported over time should be utilized.
Health Equity-Focused: For Proposed Projects addressing health inequities identified within the Applicant's description of the Proposed Project's need-base (See above, Item 1), please justify how the Proposed Project will reduce the health inequity, including the operational components (e.g. culturally competent staffing). For Proposed Projects not specifically addressing a health disparity or inequity, please provide information about specific actions the Applicant is and will take to ensure equal access to the health benefits created by the Proposed Project and how these actions will promote health equity.

KEY TERMS AND CONCEPTS

"Health Disparity" means a difference in health that is associated with economic, social, or environmental disadvantage. Health disparities adversely affect groups of people who have faced greater social and economic obstacles to health (Braveman 2014) [2].
"Health Inequities" means differences in health that are avoidable, unnecessary, and unjust (Whitehead, 1992)[3].

[2] Braveman P. "What are health disparities and Health Equity? We need to be clear." Public Health Reports 2014 Jan-Feb: 129 (Suppl 2): 5-8.

[3] Whitehead M. The concepts and principles of equity and health. International Journal of Health Services 1992; 22:429-45.

"Health Equity" means the principle that underlies the commitment to reduce health inequities and its determinants (Braveman 2014). Striving for health equity means working towards the highest standards of health for all people. This requires giving special consideration to the needs of those individuals whose social conditions create a greater risk of poor health (Braveman 2014).

"Health Value" means a measure of health outcomes achieved relative to cost (Porter 2010)[4].

"Health Outcomes" means the effects that a process has on the people it targets (WHO). Measures of health outcomes include mortality, disability adjusted life years (DALYs), incidence/prevalence of health-related behaviors and risk factors, receipt of evidence-based preventive measures, and subjective well-being and life satisfaction (Kottke 2016)[5].

Specifically, Applicant will address the Public Health Value of the Proposed Project articulating the Evidence Base, the Outcome Orientation, and the manner in which the proposed project will address health inequities. After addressing each individually, question1(b)(iv) offers the opportunity for Applicants to provide additional information to demonstrate that the Proposed Project will result in improved health outcomes and quality of life of the Applicant's existing Patient Panel, while providing reasonable assurances of health equity.

The third part of this Factor 1 addressed Operational Objectives – that is evidence that the Proposed Project will operate efficiently and effectively by furthering and improving continuity and coordination of care for the Applicant's Patient Panel, including, how the Proposed Project will create or ensure appropriate linkages to patients' primary care services. Part of this requires evidence of consultation, both prior to and after the Filing Date, with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project.

As the final part of this Factor 1, Applicants must describe the process through which Applicant determined the need for the Proposed Project. For assistance in responding to this portion of the Application, Applicant is encouraged to review *Community Engagement Standards for Community Health Planning Guideline*. Complete applications will include evidence of sound Community Engagement and consultation with the Patient Panel, throughout the development of the Proposed Project. The community engaged in this step should be representative of the communities impacted by the Proposed Project, which, at a minimum, shall include the Patient Panel and any adjacent residents or resident groups. For the effected community, the minimum necessary level of

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[4] Porter M. "What is value in healthcare?" New England Journal of Medicine Dec 2010; 363(26): 2477-2481.

[5] Kottke T, et. al. "New Summary Measures of Population Health and Well-being for Implementation by Health Plans and Accountable Care Organizations." National Academy of Medicine. July 7, 2016.

engagement for this step is "Consult". A successful Applicant will, at a minimum, describe the process whereby the "Public Health Value" of the Proposed Project was considered, and will describe the Community Engagement process as it occurred and is occurring currently in, at least, the following contexts: Identification of Patient Panel Need; Design/selection of DoN Project in response to "Patient Panel" need; and Linking the Proposed Project to "Public Health Value".

Factor (2) Health Priorities

Factor 2 addresses the impact of the Proposed Project on health more broadly (that is, beyond the Patient Panel) requiring that the Applicant demonstrate that the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation. Its intent is to create an incentive for Applicants to consider the Commonwealth's Health Priorities both in the context of developing the Proposed Project and in the development of the Community Health Initiative as required under Factor 6. In responding to this requirement, please refer to the *DoN Health Priorities Guideline* for detail.

The expectation is that, using objective data, Applicants will address how the Proposed Project supports Commonwealth Cost containment goals – in this case, by describing, for each new or expanded service, how the Proposed Project will meaningfully contribute to the Commonwealth's goals for cost containment. In this context, you may refer to Question 1(a)(iii), above.

Under certain, albeit rare circumstances, an Applicant may have a project that, in its entirety and without disaggregation meets one of the health priorities. The Health Priorities themselves (See *DoN Health Priorities Guideline* for detail) reflect Social Determinants of Health and must be addressed, in the context of the Community Health Initiative funding, using strategies that are geared to total population/community-wide prevention and/or innovative community-clinical intervention. In that event, Applicant must address, for each new or expanded service, how the Proposed Project will improve public health outcomes and how, in its entirety and without Disaggregation, the Proposed Project itself meets one or more of the Health Priorities and associated strategies set out in. the Health Priorities Guideline.

Separately, Applicants describe, for each new or expanded service, how the Proposed Project will improve public health outcomes

(c) Delivery System Transformation - Because the integration of social services and community-based expertise is central to goal of delivery system transformation, discuss how the needs of their patient panel have been assessed and linkages to social services organizations have been created and how the social determinants of health have been incorporated into care planning.

Factor (3) Compliance

Applicant certifies, by virtue of submitting this Application that it is in compliance and good standing with federal, state, and local laws and regulations, including, but not limited to M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder.

Applicant certifies, by virtue of submitting this Application that it is in compliance with all previously issued Notices of Determination of Need and the terms and Conditions attached therein.

(4) Financial Feasibility and Reasonableness of Expenditures and Costs

(a) In order to assess Financial Feasibility in compliance with this Factor, Applicant must provide evidence that it has sufficient funds available for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel.

- Certification by Independent CPA – To comply with this Factor, Applicant must submit, for Department review, certification by an independent Certified Public Accountant (CPA), executed under the pains and penalties of perjury, that the Proposed Project is financially feasible and within the financial capability of the Applicant, and where appropriate, as a matter of standard accounting practice, its Affiliates. Said certification shall be based upon the independent CPA's review of, at least, the Applicant's past and present operating and capital budgets; balance sheets; projected cash flow statements; proposed levels of financing for the Proposed Project, including a five-year financial sustainability analysis, and any other relevant information required for the independent CPA make the certification.

- Independent Cost Analysis 105 CMR 100.405(D) - Pursuant to M.G.L. c. 111, § 25C(h), the Department may require an Independent Cost Analysis ("ICA") to demonstrate that the Proposed Project is consistent with the Commonwealth's efforts to meet the health care cost-containment goals.

(b) To assess compliance with this Factor, Applicant should build upon information provided in response to Factor 1. Using that and any other information, demonstrate that the Proposed Project will compete on the basis of price, total medical expenses, provider costs and other recognized measures of health care spending.

(c) DoN staff will compare the capital costs with a recognized market measure. Fill in the Capital Costs Charts.

(5) Relative Merit

When conducting this evaluation and articulating the relative merit determination, Applicant shall take into account, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes, including alternative evidence-based strategies and public health interventions.

(6) Community-Based Health Initiatives

The Community-Based Health Initiative (CHI) or Factor 6 of the Determination of Need (DoN) process serves to connect hospital expenditures to public health goals by making investments in DoN Health Priorities.

Because access alone is insufficient to tackle health care costs, population health, and social determinants of health (SDH), DoN Applicants shall include plans for addressing state-defined Health Priorities through Community-Based Health Initiatives (CHIs). CHIs are an important mechanism through which Applicants and their local partners can support SDH and health equity.

DPH has issued three (3) sets of Guidelines to support compliance with the CHI requirement in Factor 6:

- The *Community-Based Health Initiative (CHI) Planning Guideline* describes the processes to comply with Factor 6. Applicants should read this document first. Review Table 1 and the CHI Planning Steps and Implementation section for a description of which forms are required at the time of Application. and also understand the Community Engagement requirements that must occur in anticipation of and before this Application is filed.

- The *Community Engagement Standards for Community Health Planning Guideline* provides standards for and evaluation of public participation and Community Engagement, and the connections with other community health planning activities. The following documents are required, depending upon the financial size of the proposed project, at different stages in the Application Process (Table 1 and the CHI Planning Steps and Implementation section of the CHI Planning Guideline describes which of these forms are required at the time of Application):

    - The *Community Engagement Plan;*
    - The *Community Engagement Applicant Self-Assessment* form; and,
    - The *Community Engagement Stakeholder Assessment* forms.

- The *DoN Health Priorities Guideline* defines the six (6) social determinants of health (SDH) selected by DPH as Health Priorities pursuant to 105 CMR 100.000 and establishes criteria for strategy selection that ensures strategies are evidence-informed, impactful, and designed to address one or more of the DoN Health Priorities. The selection of a strategy(ies) to impact the DoN Health Priorities is to occur ***after*** a DPH approved community engagement process, and may also occur following issuance of a Notice of Determination of Need, if approved. The Applicant will be required to complete and submit the *DoN Health Priority Strategy Selection* form.

To operationalize its obligations under Factor 6, the Applicant should refer to the Guidelines. Within the guidelines please pay special attention to the timelines and steps that will be required based upon the amount of funds committed under the CHI. While each Applicant's readiness to comply with these Guidelines will differ, DPH recommends making contact with staff from the Bureau of Community Health and Prevention (BCHAP) at least two months prior to submitting the Application to review the necessary forms and processes. All Applicants are required to submit *Community Engagement Stakeholder*

Assessment forms at the time of Application which requires the Applicant to contact stakeholders, provide the necessary forms and ensure those forms are submitted to DPH.

BCHAP staff can be contacted at DONCHI@state.ma.us.

DoN-Required Services and DoN-Required Equipment

Maintenance or replacement of existing equipment defined as DoN-required shall not first require a Notice of DoN.

For any new, additional, expansion or conversion of a DoN-required Service and/or DoN-required Equipment Applicant shall, in addition to providing the required Information and supporting documentation consistent with 105 CMR 100.210 (Factors 1-6), address with specificity the manner in which an approval of this Application for a DoN-Required Services and DoN-Required Equipment, if received, would:

- Lead to improved patient health outcomes (Quality);
- Result in a demonstrable increase in access, including but not limited to a decrease in price (Access);
- Result in a reduction in the Commonwealth's Total Health Care (Cost); and

In addition, discuss how the DoN-Required Services and DoN-Required Equipment will impact Health Systems Sustainability, that is, the financial viability of health care providers that represent critical access points for underserved residents.

Transfer of Ownership 105 CMR 100.735 - Is this an application filed pursuant to 100 CMR 100.735?

Within the context of the response to each of the Required Factors 1, 2, 3, and 4, consider and discuss how the proposed transaction will affect the manner in which Applicant serves its existing Patient Panel in the context of value (that is cost and quality), and describe the impact to the Patient Panel in the context of Access, Value (price, cost, outcomes), and Health Disparities.

If this application is accepted as a Transfer of Ownership, then it is exempt from review under each of Factors 5 and 6.

Ambulatory Surgery 105 CMR 100.740(A) -

If Applicant is a Freestanding Ambulatory Surgery Center within the Primary Service Area an independent community hospital, Applicant must please provide, as an attachment to this Form, evidence that the Proposed Project is operating in a Joint Venture with said independent community hospital or a letter of support signed by the chief executive officer and board chair of the independent community hospital in the Primary Service Area in which the project is proposed.

Capital Costs

In compliance with Factor 5, Applicants must provide a comprehensive list of all components of Estimated Capital Expenditures. Capital Expenditure as defined in the Regulations includes the site acquisition cost of land and buildings or fair market value of land and buildings if leased (capital or operating) or donated, the total cost of construction including all site improvements, the cost of all capital equipment or fair market value if leased (capital or operating) or donated, the cost of all professional fees associated with the development of the project, including fees for architectural, engineering, legal, accounting, feasibility, planning and financing services, any fee associated with financing including any bond discount, and the interest cost to be incurred on funds borrowed during construction (but not including the on-going interest expense of permanent financing).

The estimate to be computed must be based on costs and interest rates, which assume commencement and/or implementation of the project as of the date of application; therefore, the estimate should *not* include inflation up to the *anticipated actual* commencement and/or implementation date. (Where appropriate, an inflationary allowance is applied later during the DoN Staff's monitoring of the approved project.)