

DoN Project Number	17122113-TO
Applicant Name	Reliant Medical Group, Inc.
Applicant Address	630A Plantation Street Worcester, MA 01605
Filing Date	December 22, 2017
Submission Date	December 22, 2017
Type of DoN Application	Transfer of Ownership
Total Value	\$9.3million
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	Not Applicable
Staff Recommendation	Approval
Public Health Council (PHC) Meeting Date	March 6, 2018

The Applicant is Reliant Medical Group, Inc. (Reliant) a large physician practice based in central Massachusetts. Reliant is the sole corporate member of The Endoscopy Center, LLC d/b/a The Endoscopy Center (TEC) and Surgical Eye Experts, LLC,(SEE) both single specialty ambulatory surgery centers (the ASCs). Under the proposed project, Collaborative Care Holdings, LLC (CCH), a subsidiary of Optum- a subsidiary of United Health Group Incorporated (OptumCare), will acquire certain assets, and corporate control of Reliant (the Transaction). While Reliant will continue to be the sole member of the acquired assets, including the ASCs, the control of Reliant will change. That is the basis for this Determination of Need (DoN) application. The terms of the Transaction also provide that OptumCare will provide, through a management services organization, administrative services to the ASCs, and has committed to funding certain capital projects for the ASC. The Parties do not contemplate any change in the ASCs' services nor any price or service impacts on the patient panels of the ASCs as a result of the Transaction.

The Applicant requests a Determination of Need (DoN) pursuant to 105 CMR 100.735 (Transfer of Ownership). Transfers of Ownership are reviewed subject to M.G.L. c.111 section 51 and 53 and the regulation promulgated thereunder, specifically, 105 CMR 100.735 which provides in relevant part that “no Person shall be issued an Original License for ...a Freestanding Ambulatory Surgery Center... unless the Department has first issued a Notice of Determination of Need for such Proposed Project at the designated Location.” Transfers of Ownership are subject to Factors 1, 3, and 4 of the DoN regulation and certain standard conditions which are set out in Attachment 1.

The transaction that is the subject of this DoN was subject to the filing, with the Health Policy Commission (HPC), of a Notice of Material Change. HPC conducted a preliminary review of the transactions based on available information and elected not to proceed with a Cost and Market Impact Review (CMIR).

The Parties

Reliant is located in and serves the communities of the Central and MetroWest regions of Massachusetts and, together with its subsidiaries, has more than 500 employed clinicians (i.e., physicians and other clinicians, such as nurse practitioners); approximately 2,600 total employees; and provides care to more than 320,000 patients in 27 locations in the Central and MetroWest regions of the Commonwealth, including The Endoscopy Center (TEC) and Surgical Eye Experts, LLC, (SEE) (collectively, the ASCs).

OptumCare is a subsidiary of UnitedHealth Group Incorporated (“UHG”)¹. UHG is a publicly traded company which offers pharmacy care services, information and technology-enabled health services, and care delivery services and solutions through its OptumCare division; and UnitedHealthcare, which provides health care coverage and benefits services.

OptumCare describes itself as physician led, patient-centric, and data driven. OptumCare offers management services, data analytics, and other technical capabilities which it states help improve efficiencies, assist care providers in adopting new approaches and technologies that improve collaboration and coordination, and help providers transition from traditional, fee-for-service care delivery to performance-based delivery and payment models. The parties state that there is a natural synergy between Reliant’s experience in value-based care and the OptumCare platform.²

The Transaction

Following the closing of the Transaction, the current Reliant Board of Trustees will be replaced by a new Board of Directors. Initially, the new Board of Directors will be comprised of two Reliant physician employees appointed by Reliant (the Reliant-Appointed Directors), two individuals appointed by OptumCare (the OptumCare-Appointed Directors), and the CEO of Reliant (the CEO) (serving ex officio with vote) who will be appointed by Optum. During the five year period following the closing, the Reliant-Appointed Directors will have the authority to fill vacancies among the Reliant-Appointed Directors and to remove Reliant-Appointed Directors. During that period, the Board may act by simple majority vote of the Directors, except that certain significant actions (such as approvals of mergers, consolidations, dissolutions) would require the presence and affirmative vote of at least one OptumCare-Appointed Director.

Reliant will enter into a long-term Administrative Services Agreement with Reliant MSO, LLC (“Reliant MSO”), an OptumCare affiliate, which will provide administrative services to Reliant, including the ASCs,

¹ UnitedHealthcare contracts with Massachusetts providers including UMass, Hallmark Health, Steward Health Care System, and Lahey Health, and provides health care benefits to employers and employees including Raytheon, Fidelity, Pfizer, Oracle, Wellington, and General Dynamics.

² Other OptumCare operations in Massachusetts include: OptumCare also operates approximately 500 urgent care and primary care clinics in 52 markets and over 200 surgical centers nationwide. The surgical centers are operated through OptumCare’s affiliate, Surgical Care Affiliates, Inc. (“SCA”). Another OptumCare affiliate, MedExpress Urgent Care, P.C. - Massachusetts, currently operates seven freestanding urgent care clinics in Massachusetts. All Massachusetts MedExpress locations are licensed by the Department of Public Health (the “Department”), Division of Health Care Facility Licensure and Certification. Two other OptumCare affiliates currently provide services in Massachusetts. Inspiris Services Company provides medication management services and post-hospitalization transition services in Massachusetts under the name “Dovetail Health.” Dovetail Health currently provides these services as a participating provider in an Accountable Care Organization led by Lahey Health. Optum Health Care Solutions LLC (f/k/a Optum Health Care Solutions, Inc.) provides on call nursing services to patients of Lahey Health. Nationally, OptumCare partners with over 21,000 physicians in its integrated systems, and its affiliated practices employ over 6,000 physicians, nurse practitioners, and physician assistants. In Massachusetts, OptumCare has 1,306 employees and, along with UnitedHealthcare, serves approximately 490,000 Massachusetts residents.

on a fair market value basis. Reliant will retain authority for all clinical matters. The CEO will also serve as the CEO of Reliant MSO and, in that capacity, will report to OptumCare leadership.

The Applicant asserts that, without the Proposed Project, Reliant's future is, in the best case, one of managed decline. The Proposed Project, according to the Applicant, will enable Reliant to continue to operate and innovate. OptumCare has committed to supporting and enhancing Reliant's ongoing population health management efforts by providing a significant capital commitment and access to OptumCare's programs and infrastructure. The Applicant asserts that these resources will benefit Reliant's patients and improve Reliant's ability to partner with payers to slow the growth in health care costs. The Applicant asserts that this Transaction, if approved, will provide resources to allow Reliant to bolster provider recruitment efforts and contribute to provider retention.

Analysis

This analysis and recommendation reflect the purpose and objective of DoN which 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, advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation" 105 CMR 100.001.

Transfers of Ownership are subject only to factors 1, 3, and 4 of the DoN regulation and are exempt from factors 2, 5, and 6. This Staff Report addresses each of the applicable factors in turn.

Factor 1

Factor 1 requires that the Applicant establish that the project will: meet a demonstrated need by the existing patient panel; add measurable public health value in terms of improved health outcomes and quality of life of the existing patient panel, while providing reasonable assurances of health equity; improve continuity and coordination of care including appropriate linkages to patients' primary care services; be characterized by sound community engagement throughout the development of the proposed transaction; and be competitive on the basis of price, total medical expense (TME), provider costs, or other recognized measures of health care spending. 105 CMR 100.210(A)(1)

Patient Panel and Need

The majority of Surgical Eye Experts's patients are between 50-89 years of age. They present, predominantly, for cataract surgery, and care is generally reimbursed through Medicare. For the period 2015 through November 30, 2017, SEE patients came from over 180 communities, largely from the Central Massachusetts region. Over this period, 26% of SEE's Patient Panel resided in Worcester. Further, 5% of the Patient Panel resided in each of Shrewsbury and Auburn, 4% in Leominster and Millbury, and 3% resided in each of Holden, Fitchburg and Spencer. Together, residents of these locations comprised 53% of SEE's Patient Panel. Residents of each of the remaining communities accounted for 2% or less of SEE's Patient Panel.

The Endoscopy Center provides endoscopic procedures, predominantly colonoscopies. Colonoscopies are recommended for individuals aged 50 and over. The majority of TEC's patients are between 50-79 years of age. For the period 2015 through November 30, 2017, 99% of TEC's Patient Panel resided in Central Massachusetts. Over this period, 22% of TEC's patient panel resided in Worcester. Five percent of the TEC patient panel resided in Shrewsbury, 4 % in each of Auburn, Leominster and Millbury, and 3%

resided in each of Holden, Fitchburg, Spencer, Oxford and Webster. Together, residents of these locations comprised 54% of TEC's patient panel. Residents of each of the remaining communities accounted for 2% or less of TEC's patient panel.

The patient panel of each of the ASCs is characterized by the common health concerns and issues that each of the ASCs address: particularly, vision loss and colorectal cancer. Early detection and treatment is important not only for overall patient health, but to maximize the cost-effective delivery of care. Reliant argues effectively, in its Application, that the Transaction is likely to strengthen the ability of SEE and TEC to meet the needs of current and future patients requiring the outpatient surgical services they provide. The Applicant argues that OptumCare brings added resources and processes mined from an internal panel of nearly 21,000 providers across 12 different markets and that the affiliation will result in collaboration and coordination which will provide Reliant with access to additional data and thought leadership from OptumCare-affiliation practices across the country.

Public Health Value

The DoN program is designed to "ensure that resources will be made reasonably and equitably available to every person within the Commonwealth at the lowest reasonable aggregate cost" 105 CMR 100.001. As required by factor 1, any DoN applicant must show that the project will add measurable public health value in terms of improved health outcomes and quality of life for the Applicant's existing Patient Panel, with a focus on health equity. 105 CMR 100.210(A)(1)(b).

Reliant asserts that the Transaction generates public health value by improving coordination of care, and because, as a general rule, ASCs provide services at lower costs to the payer, with fewer incidents of infection (vs. a hospital), while maintaining high quality.³ Further, the Applicant asserts that OptumCare's analytics capacity will enable the Reliant providers to more accurately identify patients who would benefit from having a procedure provided at an ASC; and to track outcomes and adverse events.

The Applicant reports that as part of the Transaction, OptumCare has committed to work with Reliant to support the implementation of two key strategic initiatives that will allow Reliant to reorganize its care model to better and more efficiently and cost-effectively care for its patients. These two strategic initiatives are the Care Transformation Initiative ("CTI") and Master Facilities Plan ("MFP"). The CTI will, the Applicant asserts, support the existing focus on coordinated care in which Nurse Care Managers help identify and facilitate appropriate care for patients who have been identified as being in the top 10% of medical complexity, taking referrals from primary care providers and nursing staff, and using predictive analytics and claims data showing high utilization patients. The MFP is a comprehensive plan for the modernization and, in many cases, relocation of Reliant care delivery locations to a centralized facility designed and built to support the effective implementation and ongoing operation of the CTI.⁴ The Applicant asserts that these initiatives are essential to keep Reliant, including the ASCs, in a position to

³ *Benchmarking study of 1,000,000 surgeries in ASCs demonstrates minimal surgical site infections, emergency department visits and readmission rates*, Becker's ASC Review, August 24, 2017, available at <https://www.beckersasc.com/benchmarking/benchmarking-study-of-1-000-000-surgeriesin-asc-demonstrates-minimal-surgical-site-infections-emergency-department-visits-and-readmission-rates-2.html>. And See, ASC Quality Collaboration, ASC Quality Collaboration Quality Report, 2nd Quarter 2017, available at <http://www.ascquality.org/qualityreport.cfm.74549040v>.

⁴ SEE is not relocating as part of the MFP, as its current facility will enable it to effectively reach the CTI goals. In 2019, TEC will relocate from its current location to 385 Southbridge Street, Auburn (approximately 9 miles from its current location). TEC's future transfer of site project will necessitate the filing of a Notice of Transfer of Site to the DoN Program pursuant to 105 CMR 100.475(A).

meet patient needs while remaining economically viable, particularly in the emerging risk-sharing delivery and reimbursement healthcare system.

Reliant's population health department has outreach coordinators who contact patients who are overdue for health maintenance screening and/or disease management actions such as diabetic lab tests. Patients are also contacted post hospital discharge to coordinate follow-up appointment scheduling. Many of these alerts will, the Applicant asserts, allow Reliant to better control TME while raising its quality measures. The Applicant asserts that the OptumCare platform will give Reliant access to additional care management/disease management programs to enhance these current efforts.

Information regarding clinical outcomes and patient satisfaction at SEE and TEC is tracked currently, and both reflect high quality care. OptumCare and Reliant will continue to measure key metrics of satisfaction and outcome. OptumCare will assist Reliant, including SEE and TEC, in undertaking studies to enhance its current efforts to track patient outcomes and implement improvements. As an example, OptumCare relies heavily on the Net Promoter Score ("NPS"), which measures how likely a patient is to recommend an organization. In addition to providing access to clinical resources and best practices, OptumCare will work closely to integrate Reliant into its NPS system so that Reliant can track performance across its care delivery platform, including the ASCs, and learn from high achieving providers that participate in the NPS system.

Equity

The Parties assert that they are aligned in their commitment to assuring the availability of ambulatory surgery services for this patient population; that Reliant plans to continue to contract with MassHealth ACOs; and that following the transaction, Reliant, including the ASCs, will continue to provide equal access to its services regardless of patients' ethnicity, gender, sexual orientation or preference, age, or disability. Reliant asserts that it understands the importance of culturally competent care in the ambulatory surgery center setting and that SEE and TEC currently do, and will continue to provide significant language support to patients, and to meet any unique needs based on cultural norms for patients.

According to the Parties, the Transaction will give Reliant access to OptumCare's resources to assist Reliant in the delivery of culturally competent care, including assistance in recruiting an ethnically and racially diverse workforce; and support in the continuing development of training and education programs that Reliant views as necessary to address the needs of its Patient Panel and the local population.

Competition on Price, Costs, TME

The Applicant points out that the ASCs operate more efficiently than hospital-based locations offering similar procedures. The Applicant states that, in general, hospital-based operating room turnaround time is considered efficient at approximately 30 minutes. Turnaround time at SEE averages 8-10 minutes, and TEC has an average turnaround time of 5 minutes. In the context of fees and rates, ambulatory surgery centers are paid under the lower Medicare fee schedule than hospital outpatient services. Since most commercial payers set their fee schedules relative to Medicare, ambulatory surgery centers provide cost savings for commercial patients as well.

Because SEE and TEC are part of Reliant's integrated care delivery model, they are able to provide Reliant physicians with sufficient, timely access to operating rooms that Reliant requires in order to

meet the volume of need for the services that SEE and TEC provide, within the Reliant patient panel. As such, SEE and TEC provide critical access points for Reliant's patients.

Reliant anticipates that, over time, OptumCare's resources and support - including data to inform ongoing clinical and service improvements, and to demonstrate the effectiveness of delivery and outcomes - will result in improved access to and a reduction in TME for services provided at the ASCs. Although the ASCs are paid under a standard global surgical fee schedule model, the Applicant is a party to risk-based contracts with various health plans. Under these models, Reliant is paid based on both achieving quality targets and reducing the total cost of care.

Community Engagement

Reliant asserts that its physician leaders were actively involved in the exhaustive process for the selection of a strategic partner. Prior to announcing the transaction publicly, Reliant's physicians were fully informed regarding the proposed affiliation with OptumCare. When presented with the definitive plan for partnership with OptumCare in spring 2017, all 224 of Reliant's physicians who were present at the members' meeting voted in favor of the transaction. Prior to this formal vote, Reliant also held meetings with each clinical department and held two all-employee town hall sessions and one session focused exclusively for non-physician providers.

In connection with the public announcement of the transaction, Reliant and OptumCare undertook the following community engagement:

- All Reliant employees (physicians and non-physicians) were notified via an all-employee email of the signing of the transaction agreement on 11/27/17.
- Key community partners were informed of the signing of the transaction agreement on 11/27/17 via personal phone calls from Reliant's CEO, Dr. Tarek Elsayw. The call list included the Worcester City Manager, key payers, and hospital resources.
- A joint (Reliant and Optum) news release announcing the progress of the transaction was sent to local and regional media on 11/27/17.
- A voluntary, all-employee Town Hall conference call was held on 12/14/17. The content focused on high-level information about the future, post-close organizational structure, as well as the impact on 2018 health and welfare benefits.

Factor 3: Compliance

The Applicant certifies, 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, and in compliance with all previously issued notices of Determination of Need and the terms and conditions attached therein.

Factor 4: Financial Feasibility

The DoN regulation at 105 CMR 100.210(A)(4) requires that an Applicant for a DoN provide "sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel and that the Proposed Project is financially feasible and within the financial capability of the Applicant." Factor 4 requires that the documentation provided in support of the Department's finding shall include an analysis of the parties' finances, completed by an independent Certified Public Accountant (CPA Report).

The CPA Report includes an “analysis of the five year financial projections for Reliant, for the fiscal years ending in 2017 through 2021 (the Projections) and supporting documentation in order to render an opinion as to the reasonableness of assumptions used in the preparation and feasibility of the Projections”. The CPA report reviews key metrics that fall into three primary categories: profitability, liquidity, and solvency. The report analyzes projected revenues, reviewing the underlying assumptions upon which the Applicant relied and opines that the revenue growth projected by the Applicant reflects a reasonable estimation of future revenues of Reliant. The report analyzed each of the categorized operating expenses for reasonableness and feasibility as it related to the projections and found that the projections of expenses are, as well, reasonable. In terms of the feasibility of the proposed projects, the Projections exhibit, according to the CPA analysis, a cumulative operating EBITDA surplus of approximately 3.3% of cumulative projected revenue for the five years from 2017 through 2021 and, based upon the CPA’s review of the relevant documents and analysis, the CPA determined that the anticipated operating surplus is a reasonable expectation, based upon feasible financial assumptions. The Report concludes, “Accordingly, we determined that the projections are reasonable and feasible and not likely to have a negative impact on the patient care or result in a liquidation of assets of Reliant.”

Factor 5 and 6

Factors 5 and 6 are not applicable to transfers of ownership.

Findings and Recommendation

Pursuant to 105 CMR 100.735, the staff recommends approval of the proposed project. Any approval is subject to all standard conditions and to 105 CMR 100.735(D)(3) relative to noncompliance.

With specific reference to standard condition 105 CMR 100.310(L), which requires annual reporting by Holders, reporting shall include updates on implementation of the Care Transformation Initiative (“CTI”) and Master Facilities Plan (“MFP”), as well as an affirmation that any changes in the payer mix have not had a negative consequence on patient access.

Attachment 1

LIST OF DoN FACTORS and STANDARD CONDITIONS RELEVANT TO TRANSFERS OF OWNERSHIP

Only Factors 1, 3, and 4 apply to transfers of ownership.

105 CMR 100.210(A) The Department shall determine that need exists for a Proposed Project, on the basis of material in the record, where the Applicant makes a clear and convincing demonstration that the Proposed Project meets each Determination of Need Factor set forth within 105 CMR 100.210, unless otherwise expressly specified within 105 CMR 100.000.

[Factor] 1 Applicant Patient Panel Need, Public Health Value, and Operational Objectives.

- a. The Applicant has demonstrated sufficient need for the Proposed Project by the Applicant's existing Patient Panel;
- b. The Applicant has demonstrated 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, while providing reasonable assurances of health equity;
- c. The Department has determined that the Applicant has provided sufficient 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, sufficient evidence that the Proposed Project will create or ensure appropriate linkages to patients' primary care services;
- d. The Applicant has provided 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;
- e. The Applicant has provided evidence of sound community engagement and consultation throughout the development of the Proposed Project, including documentation of the Applicant's efforts to ensure engagement of community coalitions statistically representative of the Applicant's existing Patient Panel. Representation should consider age, gender and sexual identity, race, ethnicity, disability status, as well as socioeconomic and health status; and
- f. The Applicant has demonstrated that the Proposed Project will compete on the basis of price, total medical expenses, provider costs, and other recognized measures of health care spending.

[Factor] 2 Intentionally Omitted

[Factor] 3 Compliance.

The Department has determined, in consultation with all Government Agencies with relevant licensure, certification, or other regulatory oversight of the Applicant or the Proposed Project, that the Applicant has provided sufficient evidence of compliance and good standing with federal, state, and local laws and regulations, including, but not limited to compliance with all previously issued Notices of Determination of Need and the terms and Conditions attached therein.

[Factor]4 Financial Feasibility and Reasonableness of Expenditures and Costs.

The Department, in consultation with CHIA, has determined that the Applicant has provided sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Proposed Project without negative

impacts or consequences to the Applicant's existing Patient Panel. Said documentation shall be completed and certified under the pains and penalties of perjury by an independent certified public accountant (CPA). Said independent CPA's analysis shall include, but not be limited to: a review of 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 to provide reasonable assurances to the Department 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; and
If the Department has determined that an independent cost-analysis is required pursuant to M.G.L. c. 111, § 25C(h), the analysis has demonstrated that the Proposed Project is consistent with the Commonwealth's efforts to meet the health care cost-containment goals.

[Factor 5 and 6] Intentionally Omitted

Standard Conditions that Apply to Transfers of Ownership

Only a subset of all the standard conditions set out in 105CME 100.310 apply to transfers of ownership.

105 CMR 100.310: Standard Conditions

Unless otherwise expressly specified within 105 CMR 100.000, each Notice of Determination of Need issued by the Department shall be subject to the following Conditions. The Commissioner may specify additional Standard Conditions within Guideline which shall be attached to all Notices of Determination of Need, unless otherwise specified, and which shall be determined by the Commissioner as advancing the objectives of 105 CMR 100.000. Prior to issuance, such Guideline shall be developed through a public process consistent with 105 CMR 100.440 and in consultation with applicable Government Agencies, community-based organizations, relevant stakeholders, and the Public Health Council.

(A) The Notice of Determination of Need shall be subject to administrative review by the Health Facilities Appeals Board and may be stayed by the Health Facilities Appeals Board. If the Health Facilities Appeals Board is not constituted on the date of issuance of the Notice of Determination of Need, the Notice shall be considered a Final Action subject to review under M.G.L. c. 30A.

(B) Intentionally Omitted

(C) Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization only for the Proposed Project for which the Notice of Determination of Need is made, and for only the total Capital Expenditure approved.

(D) The Notice of Determination of Need shall constitute a valid authorization only for the Person to whom it is issued and may be transferred only upon the expressed written permission of the Department pursuant to 105 CMR 100.635(A)(3), except that a Notice of Determination of Need issued for an Original License pursuant to 105 CMR 100.730 and a Notice of Determination of Need for a Transfer of Ownership pursuant to 105 CMR 100.735 shall not be transferable.

(E)-(G) Intentionally Omitted

(H) The Government Agency license of the Health Care Facility or Health Care Facilities for which, and on behalf of, the Holder possesses a valid Notice of Determination of Need, shall be conditioned with all Standard and Other Conditions attached to the Notice of Determination of Need.

(I)-(J) Intentionally Omitted

(K) If the Health Care Facility or Health Care Facilities for which the Notice of Determination of Need has been issued is eligible, the Holder shall provide written attestation on behalf of the Health Care Facility or Health Care Facilities, under the pains and penalties of perjury, of participation, or their intent to participate, in MassHealth pursuant to 130 CMR 400.000 through 499.000.

(L) The Holder shall report to the Department, at a minimum on an annual basis, and in a form, manner, and frequency as specified by the Commissioner. At a minimum, said reporting shall include, but not be limited to, the reporting of measures related to the project's achievement of the Determination of Need Factors, as directed by the Department pursuant to 105 CMR 100.210.

(M) Intentionally Omitted

(N) The Holder shall provide to Department Staff a plan for approval by the Office of Health Equity for the development and improvement of language access and assistive services provided to individuals with disabilities, non-English speaking, Limited English Proficiency (LEP), and American Sign Language (ASL) patients.

(O) The Holder shall provide for interpreter services to the Holder's Patient Panel. The Holder shall ensure that all medical and non-medical interpreters, inclusive of staff, contractors, and volunteers providing interpreter services to the Holder's Patient Panel maintain current multilingual proficiency and have sufficient relevant training. Training for non-medical interpreters should include, at a minimum:

- (1) the skills and ethics of interpretation; and
- (2) cultural health beliefs systems and concepts relevant to non-clinical encounters.
- (3) Training for medical interpreters should include, at a minimum:
 - (a) the skills and ethics of interpretation; and
 - (b) multilingual knowledge of specialized terms, including medical terminology, competency in specialized settings, continuing education, and concepts relevant to clinical and non-clinical encounters.

(P) The Holder shall require and arrange for ongoing education and training for administrative, clinical, and support staff in culturally and linguistically appropriate services (CLAS), including, but not limited to, patient cultural and health belief systems and effective utilization of available interpreter services.

(Q) All Standard and Other Conditions attached to the Notice of Determination of Need shall remain in effect for a period of five years following completion of the project for which the Notice of Determination of Need was issued, unless otherwise expressly specified within one or more Condition.

105 CMR 100.735(D) Other Conditions. A Notice of Determination of Need issued to a Holder resulting from an Application required pursuant to 105 CMR 100.735(A) shall include the following Other Condition(s):

(1) (a) Unless rescinded pursuant to 105 CMR 100.735(D)(1)(c), any Notice of Determination of Need issued to a Holder that is subject to a Cost and Market Impact Review pursuant to M.G.L. c. 6D § 13 and 958 CMR 7.00 shall not go into effect until: 30 days following HPC's completed Cost and Market Impact Review. Unless extended for Good Cause Related to Project Implementation, or as a result of an approved amendment to a previously issued Notice of Determination of Need, the Notice of Determination of Need shall constitute a valid authorization for a period of not more than three years following the approval of the Department, unless otherwise expressly noted as an Other Condition, and shall only be for the purposes of the approved project. No Notice of Determination of Need shall remain in authorization unless the Holder complies with all prescribed terms and Conditions as set forth by the Department.

(b) The Department shall receive within 30 days of issuance of the written notification made pursuant to 105 CMR 100.625(A) a written acknowledgement of receipt of such written notification by the Holder, documented in the form of an attestation, signed by the Holder's chief executive officer and board chair, and returned to the Department and all Parties of Record.

(c) Notwithstanding 105 CMR 100.735(D)(1)(a), as part of a completed Cost and Market Impact Review, the HPC may provide a written recommendation to the Commissioner that the Notice of Determination of Need should not go into effect on the basis of findings contained within the completed and publicly released Cost and Market Impact Review. Upon receipt, the Commissioner shall determine if the Cost and Market Impact Review contains information sufficient for the Commissioner to conclude that the Holder would fail to meet one or more of the specified Factors. Should the Commissioner determine that the Holder would fail to meet one or more of the specified Factors, the Department may rescind or amend an approved Notice of Determination of Need. The Department shall consider the HPC's written recommendation pursuant to the Commissioner's determination prior to the Notice of Determination of Need going into effect, and within the context of all specified Determination of Need Factors. If a Notice of Determination of Need is rescinded by the Department, the Person for which the rescinded Notice of Determination of Need was issued must file a new Application for Determination of Need, if so desired. Such Application must satisfy 105 CMR 100.210 and shall account for the concerns expressed by the Department within their findings.

(2) Intentionally omitted

(3) If it is determined by the Department that the Holder has failed to sufficiently demonstrate compliance with the terms and Conditions of the issued Notice of Determination of Need, the Holder shall fund projects which address one or more of the Health Priorities set out in Department Guideline, as approved by the Department, which in total, shall equal up to 5% of the Total Value of the approved project. In making such determination, the Department shall provide written notification to the Holder at least 30 days prior to requiring such funding, and shall provide the Holder the opportunity to appear before the Department. The Department shall consider factors external to the Holder that may impact the Holder's ability to demonstrate compliance.

(4) Upon Notice of Determination of Need issued pursuant to 105 CMR 100.735(A), where the acquired Health Care Facility is a Holder of an approved, but not yet implemented Notice of Determination of Need, the acquired Health Care Facility's unimplemented Notice of Determination of Need shall be rendered null and void, unless the acquiring Holder receives the express written approval from the Department, pursuant to a Significant Change amendment, see 105 CMR 100.635(A)(3).