DoN Project Number	17102515-TO
Applicant Name	AdCare Inc.
Applicant Address	107 Lincoln St Worcester, MA 01605
Filing Date	October 26, 2017
Submission Date	October 26, 2017
Type of DoN Application	Transfer of Ownership
Total Value	$39,155,518
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	Not Applicable
Staff Recommendation	Approval with Conditions
Public Health Council (PHC) Meeting Date	February 14, 2018

PROJECT SUMMARY AND REGULATORY REVIEW

The Applicant is AdCare Inc., the sole corporate shareholder of AdCare Hospital of Worcester, Inc., a 114 bed licensed acute rehabilitation hospital (the Hospital) for the treatment of patients with substance use disorders and medical and psychological co-morbidities, and five outpatient satellites in Boston, North Dartmouth, Quincy, Worcester and West Springfield (hereinafter the Hospital and the outpatient facilities are referred to, collectively as AdCare).[1] Under the proposed transaction Addiction Centers of America (AAC), a wholly owned subsidiary of AAC Holdings, Inc. will become the sole corporate shareholder of the Applicant. Thereafter, AdCare will be an indirect subsidiary of AAC Holdings, Inc.

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 51-53 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 Hospital 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).

[1] The Applicant also owns, and will be conveying, through this transaction, its interest in a 46-bed inpatient facility in Rhode Island and interest in other, non-DoN related SUD treatment facilities. This DoN only addresses the DoN-regulated, Massachusetts facilities which are referred to in this Report as AdCare.

1. Background

This transaction involves the transfer of certain DoN-regulated facilities in Massachusetts by the Applicant to American Addiction Centers, through a stock transfer. The Applicant is a for-profit substance use disorders (SUD) treatment provider that operates a 114 bed licensed acute rehabilitation hospital (the Hospital) for the treatment of patients with substance use disorder and co-occurring medical and/or psychological diagnoses. The Hospital consistently operates at over 92% occupancy. Seventy eight of the beds are for patients who need medically managed detoxification, who have an average length of stay (ALOS) of 4.3 days, and 36 beds are patients who need post detoxification SUD treatment with an ALOS of 6.8 days. In addition to the Hospital, it owns and operates five outpatient satellites in Boston, North Dartmouth, Quincy, Worcester and West Springfield. The Hospital and the five outpatient satellites are, collectively referred to in this Report as AdCare.

AdCare provides a full continuum of substance use disorder treatment services including inpatient and ambulatory detoxification, post detoxification inpatient rehabilitation, acute residential treatment, day treatment, intensive outpatient programming, and individual, group, and family therapy. The services align with the American Society of Addiction Medicine's (ASAM) levels of care, which are based on the science of addiction. The Hospital is the only specialty SUD provider that provides ASAM Level 4 Detox services in Massachusetts.[2]

AAC is a publically traded company that owns and operates 10 residential SUD treatment facilities, 18 outpatient centers, and 4 sober living houses. As well, it is a national provider of laboratory SUD detection testing and also conducts addiction research.

The parties assert that this transaction will create synergies which will improve upon existing care delivery systems and processes. The parties do not anticipate any adverse impact on the patient panel or changes in health care services. The parties do not anticipate changes in reimbursement rates, care referral patterns, or access to services as a result of the proposed transaction.

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, which address population need, public health value, compliance with regulatory requirements, and sufficient financial capacity for the project. Applications for Transfer of Ownership are exempt from factors 2, 5, and 6, which specifically address health care cost containment, assessment of other options, and payment to the Community Health Initiative. This Staff Report addresses each of the applicable factors in turn.

As part of the DoN review process, DoN staff worked with BSAS and MassHealth’s OBH staff, both parties of record, and consulted the Massachusetts Department of Mental Health (DMH), also a party of record. These subject matter experts provided relevant input with respect to levels of care, the

[2] Level 4 is the most acute level of care in the ASAM http://asamcontinuum.org/knowledgebase/what-are-the-asam-levels-of-care/

regulatory schemes to which the Applicant is subject, and how the issues relevant to the DoN factors should be addressed in the Staff Report and Recommendation.

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;
- Provide reasonable assurances of health equity;
- Improve continuity and coordination of care, including appropriate linkages to patients' primary care services;
- Demonstrate 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)).[3]

Patient Panel and Need

This analysis addresses that part of the Applicant's patient panel that is subject to DoN.[4] AdCare serves approximately 4,300 inpatients and around 7,200 outpatients, annually. (See chart below)

Patient Panel

Year	In-Patient	Out-Patient
2014	4,435	7,352
2015	4,338	7,174
2016	4,192	7,207

Discharge data provided by the applicant shows that in 2016, it served 579 zip codes throughout the Commonwealth, with the largest percentage of inpatients, 34%, coming from central Massachusetts where the Hospital is located. The second largest portion, 20%, comes from Boston. Outpatients tend to be more dispersed in the five geographic areas where AdCare operates its outpatient treatment facilities. AdCare's gender and racial profile generally align with the Bureau of Substance Addiction Services' (BSAS's) SUD profile;[5] 64% of the patient panel is male and 34% is female; and for racial mix, 82% is Caucasian, 10% is Hispanic, and 7% is Black or African American. The average age of a patient seeking inpatient treatment is 44; the average outpatient is 36 years old. Eighty percent of inpatients and 55% of outpatients treated at AdCare facilities are either Medicare or Medicaid recipients as shown in the chart below.

[3] In addition, Factor 1 requires that the Applicant provide evidence of consultation with the relevant regulatory agencies which, in this case has been done and, as a result will not be addressed further in the Staff Report. 105 CMR 100.210(A)(1)(d)

[4] Assets that are a part of the transaction that are in Rhode Island or that are otherwise not subject to DoN oversight are excluded from this review (see supra, fn1).

[5] Bureau of Substance Abuse Services' *Description of Admission to BSAS Contracted/Licensed Programs*, MA, FY 2014

Payer MIX		
	Inpatient	**Outpatient**
Medicare	48%	24%
Medicaid	32%	31%
Combined Gov't	**80%**	**55%**
Commercial	20%	45%

Younger patients (age 18-25) tend to present with a drug-only diagnosis, largely opioid dependence. In FY 2016, 68% in this age group presented for inpatient admission with a drug-only diagnosis. Of those patients, 92% presented with opioid dependence. By comparison, 33% of patients over 25 presented with drug only diagnosis and of them, 61% had an opioid diagnosis.

Between 2014 and 2016, AdCare experienced an increase in patients admitted for combined alcohol and substance use disorders (poly-substance), from 33% to 41%.[6] Patients admitted for poly-substance use present, predominantly, with opioid and/or alcohol addiction in combination with each other or other substances. The Applicant asserts that the presence of alcohol increases severity and acuity because alcohol dependence requires more medical intensity during the withdrawal management phase and increases the likelihood of medical complications for the patient, as compared with withdrawal from other substances without alcohol.

The Applicant states that issues of poly-substance disorders are compounded by the increased production and dissemination of more potent synthetic opioids, such as fentanyl. Drug testing to identify the specific substances present has grown in importance from both a clinical and safety perspective. AAC has expertise in research and development of new drug detection tests as well as in operating a drug testing laboratory. The Applicant asserts that this service will inform and support AdCare's work; that prescribing activity is and will continue to be accompanied by appropriate use of laboratory services including ratios of prescription to laboratory utilization; that prior to testing, the Applicant will inform patients of any testing that exceeds their insurance coverage limits; and that the Applicant will continue to be guided and informed by the ASAM protocols to protect against unnecessary testing.[7]

As the chart below indicates, co-occurring medical and psychiatric conditions are present in most patients. In 2016, 80% presented with a co-occurring psychiatric condition, and 70% of patients presented with a co-occurring medical condition. Fifty-nine percent of patients presented with both co-occurring medical and psychiatric conditions, in addition to SUD diagnosis. In 2016, 9% of patients presented with only a substance use condition.

[6] This increased prevalence of alcohol use disorders is consistent with study in the September 2017 issue of *The Journal of the American Medical Association (JAMA) Psychiatry* which noted substantial increases in alcohol use between 2001 and 2013[6] during which alcohol use increased by 11.2%, high-risk alcohol intake increased 29.9%, and diagnosable alcohol use disorders increased by 49.4% (from 8.5% to 12.7%).

[7] http://www.mass.gov/auditor/docs/audits/2013/201213743c.pdf MassHealth and others have reported on concerns over the costs associated with over testing and overcharging for drug screenings.

Prevalence Of Co-Occurring Psychiatric & Medical Diagnoses: Inpatient Admissions						
	Year and %					
Diagnosis	**2014**	**%**	**2015**	**%**	**2016**	**%**
SUD Only*	527	9%	617	10	514	9%
SUD and Psychiatric	1,774	29%	1,615	27	1,269	21%
SUD and Medical	534	9%	552	9	628	11%
SUD and both Psychiatric and Medical	3,364	54%	3,306	54	3,535	59%
Total	**6,199**	**100%**	**6,090**	**100**	**5,946**	**100%**

*Sedative/Hypnotic/anxiolytics

Impact of Co-Morbidity on Costs

At AdCare, the most frequent co-occurring medical conditions are Hypertension, Chronic pain, COPD, Hepatitis C, and Diabetes. The most frequent co-occurring psychiatric conditions are Other Anxiety, Depression, Bipolar, PTSD, and ADHD.

Co-occurring mental health disorders and medical diagnoses increase medical expenses. The Center for Health Care Strategies published an analysis of Medicaid data demonstrating that adding a SUD diagnosis to a chronic medical diagnosis, such as diabetes, coronary disease, COPD, hypertension, or congestive heart failure significantly increases annualized medical expense. For example, the annual cost for an individual with diabetes (in 2010 dollars) is $9,498. When an addiction diagnosis is added, the costs increase to $16,267. Adding a third mental health diagnosis would drive the total expense to $36,730.[8] The Applicant asserts that this transaction will offer additional resources to effectively support the management of patients who may be poorly connected with primary care and/or disenfranchised from the broader health care system.

The Applicant asserts that the high rates of poly-substance use and of the co-occurrence of medical/psychological conditions, coupled with the increasing use of opioids by the younger patients, and the significant financial and community costs all mitigate in favor of the need for the proposed transaction.

Public Health Value (Outcomes and Quality of life)

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 outcomes, quality of life, with a focus on health equity. 105 CMR 100.210(A)(1)(b).

The Applicant asserts that this transaction will provide AdCare access to important clinical and administrative infrastructure tools to track effectiveness and treatment outcomes. While AdCare has been operating the Hospital and multiple outpatient sites of different levels of care, the Applicant states that it currently lacks the information technology (IT) analytics tools to optimally measure outcomes or to be able to scale treatment models that it has found to be effective. With this transaction, the

[8] Cynthia Boyd, et al., *Clarifying Multimorbidity Patterns to Improve Targeting and Delivery of Clinical Services for Medicaid Populations*, p5, Center for Health Care Strategies, Inc., Faces of Medicaid Data Brief, December 2010.

Applicant asserts the IT infrastructure that AAC has developed as a multi-state provider will improve the collection of data to test, develop and share best practices based on a common set of outcomes metrics among their facilities. In the DoN application, AAC describes the success of its current weekly virtual meetings among its facilities through which facilities share performance metrics and the increased transparency results in benchmarking and performance improvement initiatives.

Each of AdCare and AAC collect data for a number of quality and outcomes measures that meet the requirements of their accrediting and certification agencies. In addition, AAC commissioned an independent consultant to perform a longitudinal three year study of outcomes. To date, the findings are positive with reported improved outcomes including: less family conflict, 94%; reduced medical problems, 44%; and reduced psychiatric problems, 56%. AAC plans to extend this study to AdCare.

AdCare monitors quality through several committees and meets the quality review requirements for the Joint Commission (JCAHO) and for Centers for Medicare and Medicaid Services (CMS). Additionally, it follows protocols for the levels of care of the ASAM predicated on the principle that Addiction is a brain disease and that treatment should be evidence-based using current research and should include medical, behavioral, educational, medication assisted therapy (MAT), pain management, as well as community based recovery.

The Applicant is certified by BSAS to provide MAT at all levels of care, and licensed for the delivery of hospital care (medical and psychiatric) by the Bureau of Health Care Safety and Quality (BHCSQ). Like other hospitals licensed by BHCSQ, it is not required to also obtain a DMH license as it does not accept involuntary or conditional voluntary patients. As to the level of care provided, the Applicant provided sufficient evidence to indicate that it provides services to a majority of patients with substantial poly-substance and/or co-occurring medical/psychiatric conditions which meet the criteria of level 4.0 ASAM care. In that context, the MassHealth Office of Behavioral Health (OBH) recommends that following the transaction, the Applicant maintain its ASAM level of care criteria for level 4.0 including the regular documentation, as required by MassHealth, that they are admitting and treating patients with co-occurring acute psychiatric and/or acute complex medical conditions that meet the established definition of ASAM 4.0 level of care and that the Applicant continue to comply with measures set for MAT initiation and maintenance treatment where clinically appropriate.

Finally, AdCare's providers and services align with the four recommendations of the Health Policy Commission's report on *Opioid Use Disorders in Massachusetts*, (September 2016).[9] The Applicant provided examples of programming that aligns with these recommendations including: the use of evidence-based pharmacologic treatment; community engagement, including involvement in community task forces and committees; and efforts to scale innovative models. The Applicant asserts that this transaction will fuel expansion and improvement of this programming through the resources offered by AAC.

[9] The recommendations set forth in OPIOID USE DISORDER IN MASSACHUSETTS An Analysis of its Impact on the Health Care System, Availability of Pharmacologic Treatment, and Recommendations for Payment and Care Delivery Reform, at page 5 are: 1) the Commonwealth should systematically track the impact of the opioid epidemic on the health care system and the availability of evidence-based pharmacologic treatment; 2) the Commonwealth should increase access to and effectiveness of evidence-based use disorder treatment by integrating pharmacologic interventions in the systems of care; 3) the Commonwealth should support coordinated, multi-stakeholder community coalitions to address the impact of the opioid epidemic locally; 4) the Commonwealth should test, evaluate, and scale innovative care models for treating opioid use disorder and related conditions. http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/opioid-use-disorder-report.pdf

The Applicant maintains that the well-developed clinical and management IT infrastructure offered through the affiliation with AAC will improve care coordination. As patients transition through the ASAM different levels of care, care coordination helps them to maintain their progress without gaps in service. Shared medical records improve the effective communications among case managers, doctors, therapists and patients; and other IT tools improve the effectiveness of collaboration with outside primary care resources to develop a clear follow-up plan. The Applicant reports that 70% of patients are discharged with co-morbid medical conditions. Effective care management along the continuum, including post hospital, through use of the improved clinical IT infrastructure will, the Applicant asserts, reduce readmissions and ED visits.

Public Health Value (Equity)

In 2016 AAC was recognized by the national Healthcare Equality Index[10] for effective policies and practices related to the equity and inclusion of LGBTQ patients, visitors, and employees.

The Applicant has historically designed programs that meet the specific needs its patient panel including the young adults presenting with opioid dependence, and, in support of the West Springfield community, the development of culturally and linguistically appropriate programming in Spanish. The Applicant asserts that the AAC IT infrastructure will help AdCare to identify needs and develop targeted programs.

AdCare and AAC assert that they are committed to ensuring continued equity at AdCare by continuing to provide access to MassHealth and Medicare patients in the same or increased proportion that are currently provided. AdCare hospital's payer mix is 80% government pay and it intends to contract with MassHealth ACO's, and as a material subcontractor to certified behavioral health community partners.

Public Health Value (Competition on Price, Costs, TME)

The Applicant states that this transaction will best position it to continue providing high quality, cost effective services to its patients in a performance-based reimbursement environment. The Applicant asserts that the transaction will yield economies of scale including access to IT enhancements and data analytics which will, in turn, facilitate savings by reducing the cost of care for patients with poly-substance use and co-occurring medical/psychological conditions.

The parties do not indicate an intent or desire to seek rate increases from commercial payers. AdCare's annualized 2016 total revenue of $50 million is less than1/10th of 1% of the Commonwealth's total health care expenditures. It does not appear that the transaction is of a scale or scope that it would have a material impact on the ability of AdCare or AAC to negotiate significant increases in rates.[11] Over 80% of their payer mix is government payers with rates set through the relevant agencies and not in negotiation with a commercial payer.

[10] Human Rights Campaign *Celebrating a Decade of Promoting Equitable and Inclusive Care for Lesbian, Gay, Bisexual, Transgender and Queer Patients and Their Families* https://assets2.hrc.org/files/assets/resources/HEI-2017.pdf?_ga=2.209968725.1315169771.1512581446-1908960154.1512581446

[11] This transaction is subject the filing of a Notice of Material Change (NMC) with the Health Policy Commission (HPC). HPC uses the NMC to determine whether there is sufficient evidence that the project would have a significant enough impact on the costs and market of the Commonwealth to conduct a Cost Market Impact Review (CMIR). HPC has declined to conduct a CMIR.

Community Engagement

As a publicly traded company, AAC was limited in its ability to engage in robust community engagement until the terms of the transaction were announced. Thereafter, and in response to the requirement in 105 CMR 100.210(A)(1)(e), the Applicant describes working with patient and provider groups as well as relevant regulatory and government agencies through town halls with employees, staff, and senior leadership, the Patient and Family Advisory Council (PFAC) and work with community partners and referral sources including primary care and specialty providers.

Finding – Factor 1

The Applicant has demonstrated sufficient need by its current patient panel and demonstrated that it meets the need with a focus on equity and access. The proposed transaction will provide additional treatment resources including funding and information along with clinical collaboration with AAC's other clinical sites which has the potential to improve quality of life and outcomes measurement. Additionally, the added administrative resources that AAC has will allow for economies of scale and cost savings to AdCare's operations. It is expected that AdCare Hospital will realize improved functional capabilities and operating efficiencies to help maintain low overhead expenses while improving clinical data for outcomes measurement.

The transaction can be found to result in more efficient and effective operations as a result of AAC's administrative, IT analytics and enhanced laboratory resources. The parties commit to following established best practices, as well as state and federal licensure requirements for laboratory testing, to continued access for the patient panel to services irrespective of payer, and to improvements in outcomes through access to expanded data analytics. The parties have effectively communicated with relevant stakeholders in ways that are appropriate to the nature of this transaction.

Factor 2 does not apply

Factor 3

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

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 looks at AAC Holdings, Inc. and in that context is based upon a review, for conformance with industry standards, and mathematical accuracy, of the audited financial statements, consolidated pro forma balance sheets, statements of operations and cash flows from 2015 and 2016 The CPA Report is also based upon pro-forma financial statements of AAC, AdCare, and the combined operations of AAC

and AdCare for fiscal years ending December 31, 2017 through 2022. The CPA reviewed the Applicant's financial assumptions used in preparing the five year projections, and found that those assumptions were reasonable.

Additionally, the CPA calculated ten key financial metrics and ratios that are used to determine the current and projected financial health of an entity. These financial ratios, which are metrics for liquidity, profitability and solvency, were calculated over a five year timeframe, from 2017 (actual) to 2022 (projected) with variations year over year. Analysis of projected versus actual revenues and expenses for 2017 reflect increasing net and operating margins. Additionally, after incorporating AdCare into its financial statements, the CPA report reflects that AdCare will comprise 15% of AAC's operating revenues and 13% of its operating expenses with no change projected in the mix of existing payer contracts.

The CPA Report found that following the consolidation of AdCare into AAC, the "Proposed Project and continued operating surplus are reasonable and based upon feasible financial assumptions and are not likely to have a negative impact on the Hospital's patient panel. Therefore, the Transaction, including the Proposed Project, is financially feasible and within the financial capability of AAC. "

Factor 5 and 6 do not apply

Findings and Recommendation

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

Approval shall be subject to the Standard Conditions relevant to Transfers of Ownership (see Attachment 1) and the following additional requirements which shall become conditions of the DoN:

Other Conditions

1. With respect to the AAC commissioned independent longitudinal three year study of outcomes, the Holder shall extend the outcomes assessment to AdCare in:
    a. Its first report mandated by 105 CMR 100.310(L), submit to the Department a report that details, for each of those outcomes assessments; the baseline measures; expected benchmarks; measure specifications; and the anticipated time to meet goals;
    b. Each subsequent year report those outcomes.
2. The Holder shall continue its participation in public payer contracts, maintain its current payer mix and report annually on its Medicare (fee for service and MCO), Medicaid (fee for service and MCO), and commercial payer mix.
3. The Applicant agrees to maintain its ASAM level of care criteria for level 4.0 and provide documentation, as required by MassHealth or otherwise, that they are admitting and treating patients with co-occurring acute psychiatric and/or acute complex medical conditions that meet the established definition of ASAM 4.0 level of care.
4. The Applicant shall comply with requests for chart sampling to substantiate that level of care by regulating bodies, including DPH, CMS or MassHealth.
5. The Applicant shall comply with any government or certifying body measures set for pharmacotherapy (MAT) initiation and maintenance treatment where clinically appropriate, in adherence with the level 4.0 ASAM Hospital setting criteria and along the care continuum, including that it be accompanied by complementary therapeutic services as indicated.

6. The Applicant shall attest that prescribing activity is accompanied by appropriate use of laboratory services such that ratios of prescription to laboratory utilization do not exceed appropriate regulatory or certifying body current and new benchmarks as they are established.
7. The Applicant shall, prior to testing, inform patients of any testing that exceeds their insurance coverage limits.

Attachment 1

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 Heath 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 Heath 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 to105 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.

(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).