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

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February 13, 2021

Harry Lemieux
VP of Operations and Chief Information Officer
Harrington HealthCare System
100 South St
Southbridge MA, 01550

VIA EMAIL

RE: Notice of Final Action DoN # HHS-20012012-RE

Dear Mr. Lemieux:

This shall serve as notification that, based on the information provided by the Applicant and staff analysis, and pursuant to M.G.L. c. 111, § 25C and the regulatory provisions of 105 CMR 100.000 et seq, including 105 CMR 100.715 (DoN-required Services and DoN-required Equipment), and 105 CMR 100.630(6), I hereby approve the application for Determination of Need (DoN) filed by Harrington Health Care System, Inc. (HHS or Applicant) to add one Computed Tomography (CT) unit at Harrington Hospital's Southbridge campus. The capital expenditure for the Proposed Project is $827,216 (January 2020 dollars). The Community Health Initiative (CHI) contribution is $41,360.80. This Notice of Final Action incorporates by reference the Memorandum concerning this Application and is subject to the conditions set forth therein.

In compliance with the provisions of 105 CMR 100.310 A (2) and (11) the Holder shall submit an acknowledgment of receipt to the Department (attached) and also include a written attestation of participation or intent to participate in MassHealth.

In compliance with the provisions of 105 CMR 100.310 A (12), which require a report to the Department, at a minimum on an annual basis, including the measures related to achievement of the DoN factors for a period of five years from completion of the Proposed Project, the Holder shall address its assertions with respect to all the factors.

Other Additional Conditions:

1. In order to demonstrate that Proposed Project will add measurable public health value in terms of improved health outcomes, quality of life, and to further demonstrate the need of the Applicant's Patient Panel, the Holder shall, on a yearly basis:
    a. Report on instances of Cautionary Status.
    b. Report on Door-to-CT time
2. Of the total required CHI contribution of $41,360.80
    a. $4,136.08 will be directed to the CHI Statewide Initiative
    b. $37,224.72 will be dedicated to local approaches to the DoN Health Priorities
    c. $1,654.43 will be designated as the administrative fee.
3. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $4,136.08 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
    a. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
    b. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

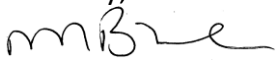
Contact for submitting contribution to the CHI Statewide Initiative:

To comply with the obligation to contribute to the CHI Statewide Initiative, please submit a check for $4,136.08 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative) **within 30 days** from the date of this Notice of Approval. Please notify DPH (CHI contact staff) when the payment has been made. Payment should be sent to:

Health Resources in Action, Inc., (HRiA)
2 Boylston Street, 4th Floor
Boston, MA 02116
Attn: Ms. Bora Toro

Ongoing compliance with the conditions and all terms of the DoN is, pursuant to the Regulation, a precondition to the filing of any future DoN by the Holder.

Sincerely,



Monica Bharel, MD, MPH
Commissioner

cc:
Elizabeth D. Kelley, Director, Bureau of Health Care Safety and Quality

Sherman Lohnes, Director, Division of Health Care Facility Licensure and Certification
Rebecca Rodman, Deputy General Counsel
Daniel Gent, Health Care Facility Licensure and Certification
Samuel Louis, Health Care Interpretive Services Coordinator, Office of Health Equity
Ben Wood, Director, Division of Community Health Planning and Engagement
Suzanne Barry, Manager Health Care Finance, Center for Health Information and Analysis
Pavel Terpelets, Deputy Director of Institutional Programs OLTSS, MassHealth
Katherine Mills, Health Policy Commission
Eric Gold, Office of the Attorney General

STAFF REPORT TO THE PUBLIC HEALTH COUNCIL FOR A DETERMINATION OF NEED	
Applicant Name	Harrington Healthcare System, Inc.
Applicant Address	100 South Street, Southbridge, MA 01550
Filing Date	October 19, 2020
Type of DoN Application	DoN-required Equipment
Total Value	$827,216.00
Project Number	HHS-20012002-RE
Ten Taxpayer Groups (TTG)	None
Community Health Initiative (CHI)	$41,360.80
Staff Recommendation	Approval with Conditions
Delegated Review	Final Action by Commissioner

Project Summary and Regulatory Review

Harrington Healthcare System submitted an application for a Proposed Project at Harrington Hospital, located at 100 South Street in Southbridge, MA, to add one Computed Tomography (CT) unit to its existing imaging service and associated renovations. The capital expenditure for the Proposed Project is $827,216; the Community Health Initiative (CHI) contribution is $41,360.

This DoN application falls within the definition of DoN-required Equipment and Services, which are reviewed under the DoN regulation 105 CMR 100.000. The Department must 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. This staff report addresses each of the six factors set forth in the regulation.

Table of Contents

Background: Harrington Healthcare System and Application Overview

The Applicant is Harrington Healthcare System, Inc. (HHS), an integrated healthcare system serving more than 25 communities across south central Massachusetts and northeastern Connecticut. Through its subsidiaries, Harrington Memorial Hospital (Harrington) and Harrington Physician Services, Inc., HHS offers its patients an integrated continuum of care from primary care to behavioral health, as well as medical and surgical specialty services, diagnostic services, and community level inpatient hospital services.

- The HHS system includes[a]: Harrington Memorial Hospital in Southbridge; Harrington HealthCare at Webster[1]; Harrington HealthCare at Charlton, Harrington HealthCare at 169, and Harrington HealthCare at Spencer in Charlton (three major medical office buildings)[2]; Harrington Physician Services[3]; UrgentCare Express at Harrington[4]; and The Cancer Center at Harrington in Southbridge.[5]
- HHS participates in the MassHealth Accountable Care Organization (ACO) program through the BMC HealthNet Plan Community Alliance.[b]

Harrington, the subject of this DoN Application, is a 103-bed community-high public payer (HPP)[6] hospital located in Central Massachusetts.[c,7] Harrington Hospital has campuses located in Southbridge and Webster, MA.[8] Harrington provides medical and surgical inpatient care, 24-hour emergency services, inpatient adult psychiatry, an intensive care unit and comprehensive outpatient services. Harrington is a Primary Stroke Service (PSS) hospital, as designated by the Massachusetts Department of Public Health.[9,d]

The Proposed Project is for the addition of a second Computed Tomography (CT) unit at Harrington's Southbridge campus which will be dedicated to emergency department (ED) patients. Multiple demands on Harrington Southbridge's single CT unit make it difficult for the Hospital to provide efficient access to CT services for ED patients, and adhere to the American Heart Association (AHA)/American Stroke Association (ASA) Get With the Guidelines – Stroke program measures for providing care to patients presenting with stroke symptoms.[10,11] Through adding a second CT unit, the Applicant will be able to provide greater access to CT services for inpatient, outpatient and ED uses, which will lead to timelier diagnosis, improved quality of care, and better treatment plans, especially for those patients with stroke symptoms.

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[1] An outpatient facility with 24/7 emergency services as well as laboratory, diagnostic imaging, primary care and specialty physicians, a sleep lab, a 16-bed adult Co-Occurring Disorders unit, and a new expanded Physical and Occupational Therapy clinic.

[2] Houses primary care and specialty physicians, diagnostic imaging, laboratory, physical therapy, outpatient behavioral health, audiology, and a Wound Care Center with hyperbaric oxygen chambers.

[3] Primary care and multi-specialty physician group, consisting of more than 60 physicians.

[4] Walk-in medical center for non-life-threatening illnesses and injuries, open seven days per week with two locations in Charlton and Oxford.

[5] Joint venture partner with 21st Century Oncology that allows patients to receive advanced, local oncological and hematology care, including chemotherapy, radiation and pain management.

[6] High Public Payer Hospitals (HPP) receive a minimum of 63% of gross patient service revenue from public payers.

[7] Total number of beds: Medical/Surgical (83), Intensive Care Unit (3), Coronary Care Unit (3), and Psychiatric Service (14).

[8] Harrington Healthcare at Webster: Inpatient Satellite (16 beds psychiatric service), and a Satellite Emergency Facility.

[9] As part of its PSS designation, a hospital must provide emergency diagnostic and therapeutic services 24 hours-a-day, seven days-a-week to patients presenting with symptoms of acute stroke. https://www.mass.gov/info-details/primary-stroke-service-pss-validation
HHS works in collaboration with the UMass Memorial Medical Center Department of Neurology TeleStroke Program, designed to provide 24/7 on-demand emergency neurology consultation to subscriber hospitals in order to improve the care of stroke patients in the community.

[10] Get With the Guidelines – Stroke Fact Sheet. https://www.heart.org/-/media/files/professional/quality-improvement/get-with-the-guidelines/get-with-the-guidelines-stroke/stroke-fact-sheet_-final_ucm_501842.pdf?la=en&hash=7FA33C71D753DF7AB1D4850451C95BBE25BEA622

[11] Get With The Guidelines (GWTG)–Stroke is an ongoing, voluntary, national registry and quality-improvement initiative.

OVERVIEW of PROPOSED PROJECT AND FACTOR REVIEW

Description of Proposed Project Component	**What's Needed to Meet Factor 1**: **Demonstration of** need; improved health outcomes and quality of life; assurances of health equity; continuity and coordination of care; evidence of community engagement; and competition on recognized measures of health care spending.	**What's Needed to Meet Factor 2: Demonstration of** cost containment, improved public health outcomes, and delivery system transformation.	Factors 3, 4 & 5[12]	**What's Needed to Meet Factor 6**: **Demonstration of** plans for fulfilling … responsibilities … in the DPH Community-based Health Initiatives Guideline.
	Staff Report finds			
	MEETS w/CONDITIONS	**MEETS**	**MEETS**	**MEETS**
Proposed project is for the addition of a CT unit dedicated to the ED to accommodate increasing volume, to decrease frequency of cautionary status[13,14,e], and to decrease wait times for imaging in the ED.[15]	• Reporting on instances of cautionary status • Reporting on door-to-CT time	✓	✓	✓

[12] 3: Sufficient evidence of compliance and good standing with federal, state, and local laws and regulations
4: Sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Project without negative impacts or consequences to the Applicant's existing Patient Panel
5: The … Project, on balance, is superior to alternative and substitute methods for meeting … Patient Panel needs.
[13] CMS Authorized Survey conducted at both Southbridge and Webster campuses on 7/24/-19-7/26/19 by the DPH Division of Health Care Facility Licensure and Certification Complaint Unit. The Hospital failed to ensure that Emergency Services provided at the Hospital complied with the requirements of regulation symbol §482.55 (Condition of Participation: Emergency Services) to meet the emergency needs of patients.
[14] DPH-approved Statewide Point of Entry Plans. https://www.mass.gov/lists/dph-approved-statewide-point-of-entry-plans
[15] 2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. https://www.ahajournals.org/doi/full/10.1161/STR.0000000000000158

Patient Panel[16]

Harrington Healthcare System (HHS) serves a diverse and growing Patient Panel of 80,811 patients.[17]

Patient Information

Tables 1 and 2 below present information for the Applicant, and Harrington Hospital. The tables provide important comparison information; staff notes the following observations about these data below:

- **Age** - The 19-64 age cohort comprises the majority (~62%) of HHS patients and Harrington patients. Older adults (ages 65+) make up ~21% of HHS patients and 23% of Harrington patients.
- **Race** - There was no significant variation from HHS and Harrington by race. The majority (~80%) of HHS and Harrington Hospital patients are White. Eight percent of HHS patients and 10% of Harrington patients identified as Hispanic/Latino.
- **Patient Origin** – Patient origin is similar across HHS and Harrington with the majority coming from Southbridge and then from Webster.
- **ACO and Managed Care Contracts and Payer Mix** – The payer mix is 27.6% commercial and 66.9% public payer. Approximately 64% of affiliated PCP patients are covered in risk contracts.

Table 1: Overview of Harrington Healthcare System Patient Panel and Harrington Hospital patient population (FY18-FYTD20)

	HHS System Patient Panel	Harrington Hospital Patient Population
YEAR	FY18-FYTD20	FY18-FYTD20
Total Unique Patients (N)	80,811	66,152
Gender (%)		
Male	45.7%	45.1%
Female	54.3%	54.9%
Age (%)		
0-18	16.7%	13.6%
19-64	62.3%	63.2%
65+	20.9%	23.2%
Race (%)		
White	79.9%	79.8%
Black or African American	1.3%	1.4%
Asian	0.6%	0.7%
Hispanic/Latino	8.2%	10.0%
Native Hawaiian or Other Pacific Islander	0.0%	0.0%
American Indian or Alaska Native	0.2%	0.2%
Other/Unknown	9.8%	7.9%
Patient Origin (List)	Southbridge 17.4%	Southbridge 19.3%
Primary Service Area	Webster 11.8%	Webster 12.9%
	Charlton 8.2%	Charlton 7.9%
	Dudley 7.3%	Dudley 7.5%
	Sturbridge 5.4%	Sturbridge 5.5%
	Fiskdale 2.5%	Fiskdale 2.4%
	Brimfield 2.3%	Brimfield 2.3%
	Holland 1.9%	Holland 2.0%
	Wales 0.9%	Wales 1.0%
	Out of State: 8.3%	Out of State: 7.0%

[16] As defined in 105 CMR 100.100, Patient Panel is 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 or Holder.
[17] From May 1, 2018 to April 30, 2020.

Table 2: Harrington Hospital APM Contract Percentages and Payer Mix

APM Contracts		Payer-Mix	
ACO and APM Contracts	64%	Commercial	27.6%
Non-ACO and APM Contracts	36%	MassHealth	2.6%
		Managed Medicaid	16.7%
		Commercial Medicare	22.7%
		Medicare FFS	24.9%
		All Other	6.4%

Data are derived from 10/2019-9/2020. Fiscal year is from October through September.

Factor 1a: Patient Panel Need

In this section, we assess if the Applicant has sufficiently addressed Patient Panel need for the Proposed Project.

Patient Panel Need

The Applicant attributes the need for a CT unit dedicated to the ED due to two interrelated factors:

a) To accommodate increasing overall volume for the existing scanner, which serves the needs of patients in the inpatient and outpatient setting, as well as the ED.

b) To more effectively meet the urgent imaging needs for ED patients with stroke[18] symptoms by

- reducing frequency of ED being on Cautionary Status[19]; and
- decreasing average door-to-CT time for suspected stroke patients.

a) Increasing overall volume

HHS has two locations in Massachusetts with CT scanners: the Southbridge campus and the Webster campus. From the period May 2019 to May 2020 there were 10,572 scans at the Southbridge campus and 4,678 scans at the Webster campus. The Applicant states that the CT scanner at the Webster campus is not at full capacity and the one at the Southbridge campus is nearing capacity. Wait times for scheduling CT scans is as follows: 72 hours for non-emergent outpatient CT scans on either campus, 12-14 days for interventional radiology procedures, and emergent access to imaging for inpatients. The Applicant asserts the addition of a CT unit dedicated to ED patients will improve Harrington's ability to meet the imaging needs of inpatients, outpatients, and ED patients.

Harrington's Southbridge campus ED has seen an increase in CT scans ordered as a tool for diagnosis and treatment planning. Over the past two years, there were 20,000 scans for ED patients.[20] Overall, ED usage of the single CT unit has increased 8% each year. The Applicant noted particular concern in meeting the prompt imaging needs of 400 (2%) of these ED patients who had stroke-related symptoms. The Applicant attributes additional demand on the CT unit to preventative health measures that include a low-dose CT scan for participants.[21]

[18] A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot or bursts (or ruptures). When that happens, part of the brain cannot get the blood (and oxygen) it needs, so it and brain cells die.
[19] Cautionary Status was indicated when then the Hospital was unable to use the CT scan for emergency medical treatment in patients.
[20] The CT unit in the Harrington Hospital Radiology Department is used for inpatients, outpatients, and ED patients.
[21] Harrington Early Detection Lung Cancer Screening Program, and Firefighter Program for high risk occupational hazards.

b) Address the Needs for Urgent Imaging in the ED, for patients with stroke symptoms.

Reducing Frequency of Cautionary Status. The Southbridge and Webster EDs use Cautionary Status when CT scan capability is unavailable. The Hospital (usually ED staff) calls the regional Central Medical Emergency Direction (CMED) Center to activate Cautionary Status and alert EMS to not bring patients who may require a CT scan to its ED.[22,23] The Hospital follows the same notification process when CT capability is restored. The Applicant noted that the Proposed Project is intended as part of its corrective actions following a survey which resulted in a finding of deficiencies related to its provision of emergency medical services.[24] The survey stated the Hospital utilizes the process of Cautionary Status as it is described in the Massachusetts Statewide Stroke Point-of-Entry Plan (S-PEP) notice.[25] The Hospital utilized Cautionary Status 62 times at Southbridge from 1/2/19 to 7/23/19. The rationale for utilizing Cautionary Status included: Interventional radiology procedures, computer system/software issues, CT scan maintenance, lab issues and other unspecified reasons. Currently, the CT unit in Southbridge serves ED patients, elective/scheduled scans and is used for Interventional radiology procedures. Interventional radiology procedures comprised over 50% of instances of Cautionary Status at Southbridge.[26] In response to Staff inquiry, Applicant noted the Hospital has been on Cautionary Status 74 times in Southbridge since November 2019.[27] The Applicant asserts that approximately 100 additional patients per year will be able to receive their scans at Harrington Southbridge after the addition of the CT unit.

Reducing door-to-CT time. The Applicant noted that the Hospital has received Primary Stroke Service (PSS) designation from DPH, which outlines time target recommendations for patient assessment and treatment, as well as early communication with EMS for a patient with stroke symptoms. The Applicant states the PSS Time Target Recommendations[28] and AHA/ASA Get With the Guidelines – Stroke program measures suggest that CT imaging be completed within 25 minutes of arrival to initiate timely treatment.[29] The survey indicated that the Harrington ED and Diagnostic Imaging Departments consistently identify when the measure cannot be met and take the appropriate action of activating Cautionary Status to ensure patients receive timely diagnosis and treatment at a facility with the appropriate available resources. The Applicant measures door-to-CT time and time for interpretation of the CT scan. The average door-to-CT time for suspected stroke patients in the Southbridge ED is 29 minutes over the past two years. According to the Applicant, Harrington Southbridge has been unable to meet the 25 minutes timeframe recommended by PSS Time Target Recommendations and Get With the Guidelines – Stroke due to competing demands on its single CT unit. The Applicant asserts the addition of the CT unit dedicated to the ED will help to reduce door-to-CT time.

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[22] Central Massachusetts Emergency Medical Systems Corporation (CMEMSC) is the Region II emergency medical services council and its communication center, CMED (Central Medical Emergency Direction), provides a direct communication link between ambulances and emergency departments at area hospitals.

[23] A CMED Center is an organization that provides specialized communications functions to connect, at a minimum, hospitals and medical first responders. A CMED Center will have a jurisdiction and a coverage area. https://www.mass.gov/doc/updated-massachusetts-ems-radio-communications-plan-effective-5242013/download

[24] CMS Authorized Survey conducted at both Southbridge and Webster campuses on 7/24/-19-7/26/19 by the DPH Division of Health Care Facility Licensure and Certification Complaint Unit. The Hospital failed to ensure that Emergency Services provided at the Hospital complied with the requirements of regulation symbol §482.55 (Condition of Participation: Emergency Services) to meet the emergency needs of patients.

[25] DPH-approved Statewide Point of Entry Plans. https://www.mass.gov/lists/dph-approved-statewide-point-of-entry-plans

[26] Webster does not perform Interventional radiology procedures, so it is not a reason to utilize Cautionary Status.

[27] The Hospital utilized Cautionary Status 23 times at Webster from 1/2/19 to 7/23/19, and 24 times at Webster since November 2019

[28] Primary Stroke Services Time Target Recommendations. https://www.mass.gov/doc/pss-time-target-recommendations-0/download

[29] PSS goal for the initiation of treatment (IV t-PA) is at one hour from the time of patient arrival in the Emergency Department.

Analysis

Staff concurs that there is a clear need to alleviate current capacity constraints and improve access to critical CT services for all patients (inpatient, outpatient, and ED), especially those with stroke symptoms seeking care in the ED. For those patients in particular, the need for timely treatment is dependent on prompt imaging and interpretation, which is outlined in the AHA/ASA Get With the Guidelines – Stroke program measures.[30,31] Additionally, freeing up capacity on the existing CT unit will address the CT imaging needs for all other patients. The addition of a CT unit at the Harrington Southbridge campus will decrease instances of Cautionary status and help to reduce average door-to-CT time. In order to further demonstrate the impact of the additional CT unit, staff recommends a condition reporting on instances of cautionary status, and average door-to-CT timeframe. This is fully described under conditions at the end of this report.

Factor 1: b) Public health value, improved health outcomes and quality of life; assurances of health equity

The Applicant asserts that the Proposed Project will enable it to better meet the need for timely access to CT services for ED patients, improving both health outcomes and quality of life of the Patient Panel in a number of ways:

- **Contributing to improved health outcomes**.
  - The addition of a second CT unit will improve health outcomes, patient safety, and quality of care especially for those patients with stroke related diagnosis and treatment.
- **Improved quality of life and patient experience.**
  - Increasing access to more efficient and timely CT services at Harrington will allow for patients to receive more timely imaging and care locally.

Analysis

Staff concurs that the ED-dedicated scanner is likely to improve patient outcomes among patients experiencing stoke, especially around the prompt diagnosis and treatment of stroke. AHA/ASA Get With the Guidelines - Stroke program[32] and PSS Time Target Recommendations[33] recommend best practices for stroke care and outline the critical importance of patients receiving immediate medical treatment when experiencing a stroke due to the rapid decline in brain function as a stroke progresses.[f] This includes receiving a CT within 25 minutes (door-to-CT time) and interpretation of the CT scan within 45 minutes. Rapid imaging is important for improving health outcomes[g]; patients that present and receive a CT in a timely manner may be eligible for tPA[34] (clot buster) to potentially prevent long-term cerebral damage.[35] The

[30] The Get With the Guidelines program was developed to improve adherence to evidence-based medicine. https://professional.heart.org/professional/ScienceNews/UCM_433170_Get-With-The-Guidelines-Improving-Patient-Outcomes-One-Hospital-at-a-Time.jsp

[31] American Heart Association/American Stroke Association 2018 Guideline recommend stroke patients receive a CT or MRI within 25 minutes of admission. https://www.ahajournals.org/doi/full/10.1161/STR.0000000000000158

[32] Get With The Guidelines (GWTG) is a hospital-based quality improvement initiative created by the American Heart Association (AHA) and the American Stroke Association (ASA) to improve the care of patients with cardiac diseases and stroke.

[33] Primary Stroke Services Time Target Recommendations. https://www.mass.gov/doc/pss-time-target-recommendations-0/download

[34] Intravenous Tissue Plasminogen Activator (also known as IV-tPA or Alteplase) is a thrombolytic agent (clot-busting drug). It is approved for use in certain patients having a heart attack or stroke. The drug can dissolve blood clots, which cause most heart attacks and strokes. IV-tPA is the only drug approved by the U.S. Food and Drug Administration (FDA) for the acute, urgent treatment of ischemic stroke. Available: https://www.mass.gov/info-details/information-about-stroke-and-stroke-treatment

[35] After clinical evaluation, eligible patients with acute ischemic strokes can be treated with alteplase, a drug that dissolves stroke causing clots, improving patient recovery and outcome. Evaluation for treatment involves ruling out medical contraindications and evaluation by computerized tomography (CT). Current recommendations encourage prompt evaluation and treatment of eligible patients, specifically facilities should perform a CT scan and administer alteplase treatment within 60 minutes of facility arrival. Research shows an expanded window of 4.5 hours from patient last known well to treatment is effective. Available: https://www.mass.gov/doc/massachusetts-primary-stroke-service-data-brief/download

benefit of tPA is time dependent - the AHA recommends its administration within 60 minutes of arrival to the hospital.[h,i,36] Early tPA treatment is associated with greater neurological improvement at 90 days.[j]

Dedicated to the ED, the scanner will also allow for additional use of the existing scanner for outpatient and inpatient use, which staff agrees is likely to improve health outcomes overall for numerous conditions. In response to staff inquiry, the Applicant states that physicians ordering CT scans within the system do not currently use clinical decision support tools (CDS). Presently, CT scans are ordered at the providers discretion based on clinical presentation. The Applicant asserts that it is progressing towards a CDS tool.[37]

Health Equity

The Applicant states that 42% of its patients speak a language other than English at home. Each year, professional medical interpreters spend approximately 575 hours assisting patients at HHS campuses. In April 2017, the Applicant transitioned to a 24/7 electronic interpreter platform as well as two FTEs. The Applicant uses the Stratus Interpreter Program, which has access to over 200 languages and provides a face to face secure interaction between the care provider and the patient. The Applicant's interpreter services cover imaging, including patients that will be scanned on the additional CT unit.

Social Determinants of Health (SDoH)

Through its investment in a Community Outreach Program which promotes wellness among its patients, HHS determined that transportation is a significant barrier to care for its patients. When patients receive care outside of the community at other hospitals, transportation to return back to the community is a challenge.[38] Public transportation to the region from Boston, Worcester and Springfield is limited, and patients without a car rely on taxi/uber/lyft services, which can be costly. The Applicant is participating in a transportation grant aimed at expanding public transportation in the area through the addition of stops between the Webster and Southbridge campuses. The Applicant is a member of the Boston Medical Center ACO and through this partnership, RNs, community health workers, and case managers assist its ACO members with identifying and addressing SDoH needs.

Analysis: Health Equity and SDoH

Staff finds that the Applicant's interpreter services is sufficient for patients receiving CT scans. The Applicant has sufficiently outlined, at a high level, a case for improved health outcomes and has provided reasonable assurances of health equity. Further, the Applicant has described how patients in the panel are screened for SDoH, and how linkages to social services organizations are created.

Factor 1: c) Efficiency, Continuity of Care, Coordination of Care

Continuity and Coordination of Care

The Applicant states that instances of Cautionary Status will be reduced through the addition of a second CT unit dedicated to ED patients. The existing CT unit will have additional capacity to improve access for both inpatients and outpatients. A benefit of this is that it will allow for coordination of care and patient records to stay in the HHS system. Keeping patients and their records in the system will improve HHS'

[36] These recommendations include advanced notification to the receiving hospital by emergency medical services (EMS), a single-call activation system for a stroke team, and rapid brain imaging.

[37] Starting in 2020, the Protecting Access to Medicare Act (PAMA) requires referring providers to consult AUC and to document via a CMS-qualified clinical decision support mechanism (CDSM) prior to ordering advanced diagnostic imaging services (ADIS) (including MRI CT, nuclear medicine or PET scan) for Medicare patients. A documented consult will be required to receive Medicare payment for the procedure after the educational and testing period, which is through CY 2021. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program

[38] The Applicant notes that St. Vincent Hospital is 31 minutes, 21.5 miles; UMass Medical Center is 36 minutes, 23 miles; and Baystate Medical Center is 43 minutes, 40 miles from Southbridge/Harrington.

ability to monitor the quality of care and outcomes of patients within its network, which will support greater continuity of care and increase the likelihood that treatment plans will be followed.

Results from CT scans are sent to patients' primary care providers (PCPs) for review and follow-up through electronic medical records (EMRs) in the Hospital and at Harrington Physician Services (HPS).[39] In addition, ED staff call patients with critical results that require follow-up. The Hospital upgraded its picture archiving and communications system (PACS); a technology for storing, retrieving, and sharing images produced by medical imaging technologies, in August 2019 to improve the reliability of the system, which will in turn help to reduce instances of Cautionary Status.[40]

Efficiencies in Care

The Applicant states that having a CT unit dedicated to ED patients will allow the scans to be performed more timely, which will lead to quicker diagnosis for patients presenting to the ED. A second CT unit will provide more efficiency around scheduling and performance of routine outpatient and inpatient studies as they will not be delayed because of emergency patients.

Analysis

Staff concurs that when CT capacity is increased and the provision of CT services is more efficient, delays in diagnosis and treatment can be reduced and note that guidelines for managing stroke patients require efficient access to CT services. EHR systems enable access of imaging results through picture archiving communication systems (PACS) and other patient information to primary care and specialty clinicians across a health system. EHRs with PACS improve efficiency for multi-faceted patient care. This helps to ensure that patients benefit from care coordination, better outcomes, and improved quality of life.

Factor 1: d) Consultation

The Applicant has provided evidence of consultation, both prior to and after the Filing Date, with all government agencies that have licensure, certification, or other regulatory oversight, which has been done and will not be addressed further in this report.

Factor 1: e) Evidence of Sound Community Engagement through the Patient Panel

The Department's Guideline[41] for community engagement defines "community" as the Patient Panel, and requires that at minimum, the Applicant must "consult" with groups representative of the Applicant's Patient Panel. Regulations state that efforts in such consultation should consist of engaging "community coalitions statistically representative of the Patient Panel."[42]

The Applicant stated that those consulted are from the same community from which the Patient Panel originates and are thus representative of the facility's Patient Panel.

- The Applicant engaged with the local Community Health Network Area (CHNA) 5[43] in October 2019. An HHS representative attended a meeting to update community program leaders on the Proposed Project. Approximately 25 members were in attendance. There were no questions or objections to the Proposed Project. The Applicant states that follow-up meetings will take place to update the CHNA group on the progress of the DON Application and project.

[39] Harrington Physician Services (HPS) employs approximately 90% of the primary care physicians in HHS' primary service area.
[40] The survey conducted on 7/26/2019 identified hardware/software issues as a contributor to the Hospital going on Cautionary status.
[41] Community Engagement Standards for Community Health Planning Guideline. https://www.mass.gov/doc/community-engagement-guidelines-for-community-health-planning-pdf/download
[42] DoN Regulation 100.210 (A)(1)(e). https://www.mass.gov/files/documents/2018/12/31/jud-lib-105cmr100.pdf
[43] CHNA 5 - Brimfield, Brookfield, Charlton, Dudley, East Brookfield, Holland, North Brookfield, Oxford, Southbridge, Spencer, Sturbridge, Wales, Warren, Webster and West Brookfield.

- The Application also updated HHS' Board of Directors, who are representatives of HHS's local communities. The Board expressed support of the project.

Analysis
Staff reviewed the information on the Applicant's community engagement and finds that the Applicant has met the minimum required community engagement standard of *Consult* in the planning phase of the Proposed Project.

Factor 1: f) Competition on price, total medical expenses (TME), costs and other measures of health care spending

The Applicant asserts that the Proposed Project will have no impact on provider price or total medical expenses (TME). The Applicant states that expansion of CT services is not intended to generate new volume, and notes that the addition of a CT scanner will increase patient safety and reduce wait times. In addition, increasing CT capacity will allow for more patients to receive care at HHS instead of potentially higher-priced facilities, will improve health outcomes, and reduce TME. The additional CT scans will be billed at the same rate as the existing CT unit and the scans will be read in the same manner.

Analysis
Studies show that stroke has a major impact on mortality, morbidity, and costs.[k] Positive outcomes are time sensitive and timely treatment for stroke patients can improves survival and reduce disability, which can reduce medical expenditures.[l] A reduction in healthcare utilization and spending can occur with improved access to timely care. The Proposed Project will increase timely access to CT services for potential stroke patients, and this will help to reduce the costs of care for patients with stroke related diagnoses.

Description of Suggested Conditions, FACTOR 1

As a result of information provided by the Applicant and additional analysis, staff finds that with the Conditions outlined below, the Applicant has demonstrated that the Proposed Project meets Factors 1(a-f).

Staff recommends adding two Conditions requiring specific reporting, described fully under Conditions:

1) Reporting on instances of Cautionary Status.
2) Reporting on door-to-CT time.

Factor 2: Cost containment, Improved Public Health Outcomes and Delivery System Transformation

Cost Containment
The Applicant states that the Proposed Project will help it keep care within the HHS system, and decrease the frequency of Cautionary Status. In addition, HHS participates in four risk arrangements that support Massachusetts' cost containment goals.

Analysis: Cost Containment
Staff finds that the Applicant has adequately explained how the Proposed Project aligns with the Commonwealth's cost containment goals through increasing access to high-quality, cost-effective imaging and through its risk arrangements.

Improved Public Health Outcomes

The Applicant has discussed how improved access to CT services can lead to more timely treatments that ultimately can reduce morbidity and mortality for ED patients, including those with stroke symptoms. In addition, increasing CT capacity in the ED will improve access to the existing scanner for inpatients and outpatients. These issues have been discussed earlier in this Report.

Analysis: Public Health Outcomes

As detailed elsewhere in this Report, improvements in patient health outcomes for ED patients result from efficient and timely access to CT services. Stroke is the fifth leading cause of death and a leading cause of disability in the United States.[m,n] Ischemic strokes make up 85% of all strokes in the United States.[o] Stroke is a leading cause of serious, long-term adult disability.[p,q] Receiving immediate medical treatment can minimize long-term effects of a stroke and prevent death.[r]

Delivery System Transformation

HHS had a large physician network made up of both specialty and primary care. The addition of a second CT unit will allow HHS to keep patients, including neurologic patients, in its network and improve health care delivery and outcomes. HHS participates in the MassHealth ACO Program, through the BMC HealthNet Plan Community Alliance. The Applicant states that approximately 5,200 MassHealth members are assigned to HHS through this ACO partnership plan. HHS participates in the following risk arrangements[44]:

Boston Accountable Care Organization (BACO)[45]	5,200 covered lives
United Medical ACO (UMACO)	4,700 covered lives
Fallon Senior	1,500 covered lives
Commercial ACO	6,000 covered lives (BCBS, Tufts, Harvard Pilgrim)

Analysis: **Delivery System Transformation**

Central to the goal of Delivery System Transformation is the integration of social services and community-based expertise. The Applicant has described how residents in the panel are assessed and how linkages to social services organizations are created. This has the potential to improve the continuity of care, since the Applicant has four risk contracts that aim to coordinate care across the continuum to reduce costs and improve patient experience and outcomes. As such, the Applicant has ongoing incentives to address population health needs and SDoH.

Summary, FACTOR 2

As a result of information provided by the Applicant and additional analysis, staff finds that the Applicant has demonstrated that the Proposed Project meets Factor 2.

Factor 3: Relevant Licensure/Oversight Compliance

The Applicant has provided evidence of compliance and good standing with federal, state, and local laws and regulations and will not be addressed further in this report.

[44] MCN and UMACO (upside risk). Fallon and BACO (downside risk).

[45] The Boston Accountable Care Organization is made up of 19 provider organizations, including Boston Medical Center and, Harrington HealthCare System. https://www.harringtonhospital.org/news/harrington-healthcare-system-joins-boston-accountable-care-organization/

Factor 4: Demonstration of Sufficient Funds as Supported by an Independent CPA Analysis

The CPA analysis included a review of numerous documents in order to form an opinion as to the feasibility of the Proposed Project including:

- Five Year Pro Forma Statements[46]
- FY 2018 and 2019 draft audited financial statements for Harrington Healthcare System, Inc.
- Proposed 2020 budget presentation
- Third party industry data sources[47]

During its review of the Pro-Forma, the CPA examined the underlying assumptions used by the Applicant to develop the revenue and expense forecasts. Additionally, key metrics and financial ratios for profitability, liquidity, and solvency were compared to historic performance to measure Harrington Healthcare System's (HHS) overall financial health.

The CPA reports that revenue for the Applicant includes net patient service revenue and other operating revenue. The Proposed Project is not projected to have any impact on volume, and therefore will not impact net patient service revenue. The five-year compound annual growth rate (CAGR) for total operating revenue in the Projections of 0.5 was below Harrington's revenue growth rates in FY 2018 (3.9%) and FY 2019 (1.6%). The CPA reports that the revenue growth projected by Management, which relied upon historical operations and anticipated market movements, is a reasonable estimation of future revenue of HHS.

The CPA analysis reports that operating expenses are projected to grow 2.1% in FY 2020, and then at a rate ranging from -0.03% to 0.01% from FY2021 to FY2024. The annual growth in total expenses falls within the historical range of expense growth in FY2018 (1.8%) and FY2019(-1.7%) and expenses in FY2020 reflect the budget presented to the finance committee. The Projections reflect equipment depreciating over a seven-year life and associated renovations/construction depreciating over a 4-year life. Supplies expense reflects incremental maintenance expense related to the CT scanner. The CPA reports that the operating expenses projected by Management is a reasonable estimation of future expenses of HHS.

The analysis included the impact of the capital expenditures for this Proposed Project relative to other capital expenditures included in the Projections. The Proposed Project represents 12.2% of capital expenditures in FY2020, which total 6.7M. The CPA reports that there is sufficient room to accommodate the financing for the Proposed Project with the Applicant's normal capital expenditures without the need for debt financing. In conclusion, the CPA reports "the Projections are reasonable and feasible, and not likely to have a negative impact on the patient panel or result in a liquidation of assets of Harrington."

Staff finds the CPA analysis to be acceptable, meeting the standard of Factor 4, noting Harrington Hospital's operating margin of -1.6% % for the fiscal year-to-date period ending March 31, 2020 (quarterly update) is slightly lower than its peer cohort (Community-HPP) median of -1.2% and the same as the statewide median of -1.3% based on reporting by CHIA.[48,s]

[46] FY 2020 -2024
[47] The Risk Management Association, Definitive Healthcare, and IBISWorld Industry Report.
[48] Staff relies on the CPA Analysis and CHIA reporting and does not perform its own financial analysis.

Factor 5: Assessment of the Proposed Project's Relative Merit

The Applicant asserts there is no safe and sustainable alternative for the Proposed Project to increase access to CT services at the Southbridge campus. Under current circumstances, the Hospital activates Cautionary Status when the CT unit is unavailable to ED patients. However, both inpatients and ED walk-ins experiencing stroke symptoms still require CT services and would require transfer or undergo alternate imaging options less well suited to diagnose stroke.[49] Delays in accurate diagnosing and treating stroke can adversely impact health outcomes and quality of life.[t] The Applicant asserts the Proposed Project will increase access to CT services for the Patient Panel by reducing instances of Cautionary status and wait times for CT scans.

Staff agrees that the Proposed Project is the superior option for reducing instances of Cautionary Status and facilitating the provision of care to stroke patients within the time frame that is recommended. The association that has been established between earlier treatment and outcomes reinforces the importance of accelerating diagnosis and treatment of stroke, which includes timely access to CT services.[u,v] The Applicant is purchasing a refurbished CT scanner of similar make and model and will also be renovating existing space, making the Proposed Project cost effective. As a result of information provided by the Applicant and additional analysis, staff finds the Applicant has reasonably met the standards of Factor 5.

Factor 6: Fulfillment of DPH Community-based Health Initiatives Guideline: Overall Application

Summary and relevant background and context for this application: The Applicant is applying for a DoN that will result in a Tier 1 CHI project for Harrington Hospital in Southbridge, Massachusetts. The Harrington HealthCare System is regional and serves approximately 200,000 people in Massachusetts and Connecticut. The Community Health Initiative (CHI) activity will serve the south central Massachusetts communities within the hospital's catchment area. The Applicant's Proposed Project will result in a small CHI total for a geographic area with infrequent DoN project applications.

The Applicant completed its most recent Community Health Needs Assessment (CHNA), submitted to DPH for review, in December 2019. In conducting the CHNA, the Applicant administered a broadly distributed survey, and utilized secondary data collection methods to identify assess health and healthcare needs within the system's service area.

Through document review and ongoing communication with Harrington Hospital Community Benefit staff, DPH staff have assessed community engagement efforts and will continue to work with the Applicant to ensure meaningful outreach to and decision making by populations served.

Staff have assessed Harrington HealthCare System's 2019 CHNA and determined that it is appropriate for the Applicant to do additional outreach to the populations not reached with original survey distribution. DPH staff have requested additional information from the Applicant about their Community Benefit Advisory Committee composition and decision-making structure. DPH recommends the Applicant connect with social service agencies conducting existing work with populations of focus.

[49] The survey conducted on 7/26/2019 reported that EMS brought in patient experiencing symptoms of stroke to the Webster ED when it was on cautionary status due to a miscommunication. The patient was transferred to a tertiary facility.

DPH staff further requested status updates and materials pertaining to how the CHNA will be used to identify priorities and select strategies that align with the social determinants of health (SDoH), and the DPH Health Priority framework. This will support the Applicant in ensuring appropriate stewardship of the CHI funds from this application.

The Applicant submitted a CHNA/CHIP Self-Assessment, the first under its current 2019 CHNA, and the 2019 Community Health Needs Assessment for Harrington HealthCare System.

- **In the Self-Assessment**, the Applicant provided a summary of socio-demographic data and highlights of health outcome information related to these topics. This information was derived from the 2019 CHNA, and was identified through a community survey and secondary data analysis. Using this methodology, the Community Benefit Advisory Committee identified key concerns related to health and health care. The Self-Assessment identifies partners engaged during the needs assessment process, and includes an accurate plotting of activities conducted along the Community Engagement Spectrum.
- **The Community Health Needs Assessment** was conducted in 2019 by the Harrington HealthCare System, inclusive of the Applicant's site, Harrington Hospital in Southbridge. The report contains elements specific to its broad geographic service area. In creating the CHNA for this hospital, the Applicant administered a community survey, and analyzed secondary data from various sources. Through these methods, the Applicant engaged its Community Benefit Advisory Committee and reached a small portion of the community residents served, who provided responses to the survey. The CHNA for 2019 identifies and ranks health concerns among population segments. Seniors list Dementia, Diabetes, and Heart Disease as their top three concerns respectively, while Youth/Adolescents identify Mental Illness, Substance Use, and Bullying as their three priorities. Overall concerns are Mental Illness, Substance Use, and Obesity. The CHNA begins to explore community conditions that may facilitate or hinder progress within the concerns identified, highlighting access as a key theme.

Summary Analysis: As a result of information provided by the Applicant and additional analysis, staff finds that with the conditions outlined below, and with their ongoing commitment to work with staff on the above outlined issues and based on planning timelines that staff will approve, the Applicant has demonstrated that the Proposed Project has met Factor 6.

Findings and Recommendations

Based upon a review of the materials submitted, Staff finds that, with the addition of the recommended Conditions detailed below, the Applicant has met each DoN Factor for the Proposed Project, and recommends that the Department approve this Determination of Need, subject to all applicable Standard and Other Conditions.

Other Conditions to the DoN

1. In order to demonstrate that Proposed Project will add measurable public health value in terms of improved health outcomes, quality of life, and to further demonstrate the need of the Applicant's Patient Panel, the Holder shall, on a yearly basis:
    a. Report on instances of Cautionary Status.
    b. Report on Door-to-CT time
2. Of the total required CHI contribution of $41,360.80
    a. $4,136.08 will be directed to the CHI Statewide Initiative
    b. $37,224.72 will be dedicated to local approaches to the DoN Health Priorities

c. $1,654.43 will be designated as the administrative fee.

3. To comply with the Holder's obligation to contribute to the Statewide CHI Initiative, the Holder must submit a check for $4,136.08 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative).
    i. The Holder must submit the funds to HRiA within 30 days from the date of the Notice of Approval.
    ii. The Holder must promptly notify DPH (CHI contact staff) when the payment has been made.

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