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

MARYLOU SUDDERS
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MONICA BHAREL, MD, MPH
Commissioner

August 27, 2018

Via E-mail and first class mail

Andrew Levine, Esq.
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RE: Notice of Final Action
Project No. 18042417-RE
Winchester Hospital/Shields MRI, LLC

Dear Mr. Levine:

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 100.725 (DoN Required Services and DoN Required Equipment), and 105 CMR 100.630(7), I hereby approve the application for Determination of Need ("DoN") filed by Winchester Hospital/Shields MRI, LLC (Shields or Applicant) to acquire one 1.5T MRI for a satellite of the Applicant's existing clinic at 200 Unicorn Park Drive, Woburn, MA (Unicorn Park). The satellite clinic will be located on Winchester Hospital's main campus at 41 Highland Avenue, Winchester, MA (Satellite).

This Notice of Final Action incorporates by reference the Memorandum concerning this Application and is subject to the conditions set forth therein.

Sincerely,

A handwritten signature in black ink, appearing to read "MBharel".

Monica Bharel, MD, MPH
Commissioner

cc: Sherman Lohnes, Director, Division of Health Care Facility Licensure and Certification
Rebecca Rodman, Deputy General Counsel
Daniel Gent, Health Care Facility Licensure and Certification
Mary Byrnes, Center for Health Information and Analysis
Stephen Sauter, MassHealth
Katherine Mills, Health Policy Commission
Eric Gold, Office of the Attorney General

Memorandum to the Commissioner

APPLICANT: Winchester Hospital/Shields MRI, LLC
700 Congress Street, Suite 204
Quincy, MA 02169

PROJECT NUMBER: 18042417-RE

DATE OF APPLICATION: April 30, 2018

Introduction

This memorandum presents, for the Commissioner's action, the Determination of Need (DoN) Program's recommendation in connection with a request by Winchester Hospital/Shields, LLC (Applicant) to acquire one 1.5T MRI. The Applicant operates two MRI units at its existing clinic at 200 Unicorn Park Drive, Woburn, MA (Unicorn Park). The Applicant is proposing the addition of a third 1.5T MRI unit at a satellite clinic which will be located on Winchester Hospital's main campus at 41 Highland Avenue, Winchester, MA (Satellite).

This request falls within the definition of DoN-Required Equipment and Services which are reviewed under the DoN regulation 105 CMR 100.000. This memorandum addresses each of the six factors set forth in the regulation. Pursuant to 105 CMR 100.630, this Application has been delegated by the Department for review and Final Action by the Commissioner.

Background

Winchester Hospital/Shields MRI, LLC (Applicant) is a joint venture between Winchester Hospital (WH) and Shields Imaging of Winchester, LLC (Shields) that was formed in 2013 to establish a licensed clinic in Woburn, MA (Unicorn Park). Unicorn Park provides magnetic resonance imaging (MRI)¹ services to Winchester Hospital (WH) and Winchester Physician Associates (WPA) patients, as well as to patients referred from other providers.²

Winchester Hospital (WH), a subsidiary of Winchester Healthcare Management, is a 229-bed community hospital and an affiliate of Lahey Health System, Inc. (LHS), which is a Health Policy Commission (HPC), certified Accountable Care Organization (ACO). WH provides inpatient and outpatient services as well as integrated home care to residents in northwest suburban Boston.

¹ Magnetic Resonance Imaging (MRI) is a non-invasive medical imaging procedure that uses strong magnetic fields and radio waves to produce detailed images of internal bodily structures. MRI images are used in disease detection, diagnosis, and treatment monitoring. MRI creates images without exposure to ionizing radiation which has the potential for harmful effects. MRI magnetic field strength, measured in Tesla (T), is usually between 0.5T and 3.0T.

² The Unicorn Park Clinic was set up off-site, according to the Applicant, because the WH campus could not accommodate the two MRI units needed at the time to accommodate patient volume, and lacked sufficient access to onsite-parking.

MRI is designated, under the 2017 DoN-Required Equipment and Services Guideline as equipment that warrants a case-by-case review based on DoN application-specific information due to its potential for clinically unnecessary utilization that in the aggregate, can result in a significant increase in health care spending without an associated benefit to the public in terms of better health outcomes, or access to needed care.³

WH is the only hospital in Massachusetts that does not provide MRI services at the hospital's main campus.⁴ Winchester Hospital provides its patients with access to MRI services through an arrangement with the Applicant. Inpatients and patients admitted to the Emergency Department (ED) at WH who need an MRI are transported by ambulance to Unicorn Park (2.0 miles away). During the Clinic's off-hours, patients are transported to Lahey Health and Medical Center in Burlington, MA (9.0 miles away).⁵ The expenses associated with transporting patients under the current arrangement include a \$400 flat rate for a round-trip ambulance ride⁶ and the staffing of a full-time nurse at Unicorn Park to support transported patients.⁷ This arrangement applies to all WH inpatients and ED patients, irrespective of acuity or age.

The Applicant argues that transporting WH inpatients and ED patients to Unicorn Park for MRI services increases delays and the risk of adverse health outcomes, leads to fragmented and costly care, and compromises the patient care experience. Furthermore, the Applicant states that historical volume at Unicorn Park shows a steady increase in the number of patients utilizing MRI services. Increasing volume, coupled with prioritization of WH inpatients and ED patients over outpatients, has resulted in delays and cancellations for WH outpatients seeking MRI services at Unicorn Park. The Applicant argues that having access to MRI capacity at the Satellite on the WH campus will alleviate capacity constraints; eliminate the associated risks and costs of transporting WH inpatients and ED patients from WH to Unicorn Park; and support integrated care for inpatients and ED patients at WH.

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

³ *Determination of Need Required Equipment and Services Guideline* (Rep.). (2017, January). Retrieved June, 2018, from Massachusetts Department of Public Health website:

<https://www.mass.gov/files/documents/2017/01/vr/guidelines-equipment-and-services.pdf>

⁴ Applicant surveyed each licensed hospital in Massachusetts and inquired about the location of its MRI service.

⁵ FY17, 668 scans were performed for WH inpatients, and 55 scans for WH ED patients were done following transfer to Unicorn Park. From May 2017-April 2018, 89 patients referred by Winchester Hospital physicians received MRI services at Lahey Hospital Medical Center.

⁶ The Applicant reported \$882,000 in ambulance costs between FY15-FY17 for 2,205 MRI scans performed at Unicorn Park for WH inpatients and ED patients.

⁷ A nurse is available to travel with patients transferred from Winchester Hospital to Lahey Medical Center for MRI services.

lowest reasonable aggregate cost advancing the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation” 105 CMR 100.001.

All DoN factors are applicable in reviewing a DoN-Required equipment proposed project. This Staff Report addresses each of these factors in turn.

Factors 1 and 2

Factor 1 of the DoN regulation asks that the Applicant address patient panel need, public health value, and operational objectives of the Proposed Project, while factor 2 focuses on health priorities. Under factor 1, the Applicant must provide evidence of consultation with government agencies with licensure, certification or other regulatory oversight which, in this case, has been done and so will not be addressed further in this staff report. This analysis will approach the remaining requirements of factors 1 and 2 by describing the Proposed Project and reviewing how each element complies with those parts of the regulation.

Patient Panel and Need

Patient Panel Demographics

In Calendar Year (CY) 2017, 13,542 patients visited Unicorn Park to receive MRI services.⁸ The Applicant states that the number of patients at Unicorn Park increased 10.5% between CY15 (12,253) and CY17 (13,542).⁹ In 2017, the Applicant's patient panel was 57% female and 43% male.¹⁰ The Applicant states that based on zip code data, the majority of patients receiving scans at Unicorn Park reside in Eastern Massachusetts, and more specifically, 71.0% from Middlesex County and 6.1% from Essex County. These demographics are similar to the Winchester Hospital (WH) and Winchester Physician Associates (WPA) patient panels.¹¹ The Applicant's payer mix in FY17 was: Medicare Advantage (1%), Medicaid (6%), Medicare (18%), Commercial (62%), and Other (13%).¹²

⁸ Applicant states that any community physician/provider can refer patients to Unicorn Park for MRI services. Therefore, the Unicorn Park patient panel includes Winchester Hospital patients, Winchester Physician Associate patients, Lahey patients, and patients referred by other community physicians. The Applicant states that Winchester Hospital patients make up the majority of the Unicorn Park patient panel.

⁹ The Applicant states that between May 2017 and April 2018, 89 patients referred by Winchester Hospital physicians received MRI services at Lahey Medical Center.

¹⁰ The Applicant does not collect data on race, so that information is not available for the Unicorn Park patient panel. Based on self-reporting, the racial composition of the patient panel of Winchester Hospital and Winchester Hospital Physician Organization was predominantly White or Caucasian (84.5%).

¹¹ Winchester Physician Associates (WPA) is the physician group of parent organization Winchester Healthcare Management (WHM). WPA is an affiliate of Winchester Hospital (WH). WPA doctors are members of the medical staff at WH and their patients receive medical services at WH, including emergency and imaging services.

¹² The Applicant states that 'Other' includes Champus, external collectors, the Hospital, private pay, and liability. DoN Application 18042417-RE, Attachments, at page 5.

Patient Panel Need – Increasing Utilization

The Applicant stated that the number of scans performed at Unicorn Park increased 11.2% between FY 15 (14,405) and FY17 (16,023).¹³ The Applicant also cited the increasing volume at Unicorn Park over the past three years as having further impacted timely access to MRI services. Overall utilization is up from 84% in FY15 to 89% in FY17.¹⁴ In FY15, 68% of scans performed at Unicorn Park were on time or within 10 minutes of their scheduled appointments and that percentage decreased to 59% in FY17. The Applicant implemented extended hours of operation to address the high demand for MRI services at Unicorn Park. However, the Applicant asserts that even with the extended hours of operation, the MRI machines are still operating at capacity and patients are offered less convenient times for accessing MRI services. The Applicant asserts that the increasing volume, along with the need to have a unit on-site at WH to avoid the cost and health risks associated with moving WH inpatients and ED patients to Unicorn Park support the addition of this unit, with its added capacity, at WH.

Public Health Value

The DoN regulation requires the Applicant to demonstrate that the Proposed Project will add measurable public health value in terms of improved health outcomes and quality of life for the existing patient panel, while providing reasonable assurances of health equity.

The Applicant asserts that the lack of an MRI unit on the WH campus restricts timely access to high-quality MRI services for WH inpatients, ED patients and outpatients; results in a variety of risks, delays, and care fragmentation. Applicant cites research on intra- and inter hospital transfers stating that physiological deterioration and adverse events can occur at any time during the transport process and critically ill patients are at increased risk.^{15,16} The current set-up has a negative impact on WH outpatients in terms of convenient and timely access to MRI services because WH inpatients and ED patients with more emergent healthcare needs are prioritized at Unicorn Park, which results in delays and cancellations for outpatients.

The Applicant maintains that the proposed project will increase access to high-quality MRI services in a cost-effective, efficient, and integrated manner. The Applicant affirms the importance of MRI in patient care, early diagnosis and timely treatment. The addition of an on-campus MRI unit will, the Applicant asserts, address the increasing volume and demand for MRI services more generally at Unicorn Park and WH; will eliminate the risks and delays associated

¹³ In FY17, WH ED patients represented 0.3% of MRI scans, WH inpatients represented 4.2%, and outpatients represented 95.5%.

¹⁴ In FY 17, the volume of MRI scans by procedure was: Orthopedic (45.3%), Neurologic (40.8%), Body (8.0%), Chest 4.8%, and Angiographic (0.8%).

¹⁵ Dunn, M., Gwinnutt, C., & Gray, A. (2007). Critical care in the emergency department: Patient transfer. *Emergency Medicine Journal*, 40-44. Retrieved May, 2018, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2658153/pdf/40.pdf>

¹⁶ Droogh, J. M., Smit, M., Absalom, A. R., Ligtenberg, J. J., & Zijlstra, J. G. (2015). Transferring the critically ill patient: Are we there yet? *Critical Care*. Retrieved May, 2018, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4335540/pdf/13054_2015_Article_749.pdf

with transporting WH inpatients and ED patients to Unicorn Park; and that the timely access and more integrated care may improve health outcomes and quality for the patient panel.

Equity

The Applicant looked to the 2016, Winchester Hospital Community Health Needs Assessment (CHNA), to understand and address potential barriers to accessing healthcare among its patient panel. The 2016 Winchester CHNA reported on the health-related needs of individuals living in Winchester Hospital's service area, with a particular focus on vulnerable populations.¹⁷ The Applicant states that a dominant theme within the 2016 Winchester Hospital CHNA are the social determinants of health (SDoH) facing residents living in WH's service area and the limitation they place on an individual or family's ability to maintain their health. In particular, the 2016 Winchester Hospital CHNA identified language barriers within segments of Middlesex County where a significant portion of the Applicant's patient panel reside.^{18,19} The Applicant asserts that there are a number of systems in place at Unicorn Park that address language as a barrier to care and asserts that these will continue at the WH Satellite clinic location including: access to interpreter services for patients with Limited English Proficiency (LEP), American Sign language (ASL) interpreters, video remote interpreting, and phone interpreting; and ongoing education and training in culturally and linguistically appropriate areas for staff.

Competition

Based upon the information reviewed, you can find that the project will be competitive, as that term is used in 105 CMR 100.210(A)(1)(f). The contracted rates for MRI services at Unicorn Park will be the same as those offered at the Satellite clinic on the WH campus; the MRI services on-campus will be reimbursed at the rates for an independent diagnostic testing facility (IDTF), which are lower compared to hospital-based clinic rates;²⁰ and the net annual revenue for the satellite clinic at WH will represent a statistically insignificant amount compared to imaging services provided by the state and overall healthcare spending.^{21,22,23} The Applicant also states

¹⁷ *Winchester Hospital Community Health Needs Assessment* (Rep.). (2016). Retrieved March, 2018, from JSI website: <https://www.winchesterhospital.org/File Library/Winchester Hospital/Our Promise/Winchester-Hospital-2016-Community-Health-Assessment.pdf>

¹⁸ *Winchester Hospital Community Health Needs Assessment* (Rep.). (2016). Retrieved March, 2018, from JSI website: <https://www.winchesterhospital.org/File Library/Winchester Hospital/Our Promise/Winchester-Hospital-2016-Community-Health-Assessment.pdf>

¹⁹ According to the CHNA, 19.3% of Middlesex County reports being foreign born compared to 15% of the residents in the Commonwealth and the two towns in Middlesex County, Winchester and Woburn, reporting the highest percentage of foreign born also reported the highest percentages of residents speaking languages other than English at home.

²⁰ HPC reported that the average price in Massachusetts for an MRI of the brain with contrast is \$699 at a facility setting and \$337 at a non-facility setting (https://www.mass.gov/service-details/hpc-datapoints-issue-7-variation-in-imaging-spending#!/vizhome/imaging_final/Annualimagingsspendingperbeneficiarybystate) and that among commercial payers in Massachusetts, prices in 2015 for a knee MRI were 38% higher when performed in a hospital outpatient department compared to a non-hospital setting such as a freestanding imaging center. (<https://www.mass.gov/files/documents/2018/03/28/Cost%20Trends%20Report%202017.pdf>).

²¹ The Center for Health Information and Analysis (CHIA) reported \$59 Billion in total healthcare expenditures (THCE) in 2016 (<http://www.chiamass.gov/assets/2017-annual-report/2017-Annual-Report.pdf>).

that the on-campus MRI unit will eliminate the costs associated with inter-facility transport and that to the degree that transportation and attendant complications or risks can lengthen the inpatient stay, this can reduce healthcare expenditures for payers and patients.^{24,25}

The addition of one 1.5T MRI at a satellite clinic on the WH campus will free up capacity at Unicorn Park to support timely access to MRI services for WH outpatients and the Applicant's projected incremental volume increases among its patient panel. The added capacity at Unicorn Park creates the potential for additional increases in volume from patients in the area in search of more convenient access to MRI services. While a small increase in Total Medical Expenses (TME) as a result of the proposed project is possible, the increase is expected to represent only a small percentage of the Commonwealth's TME. In addition, third-party payer programs for managing imaging utilization, including prior authorization, also support the goal of minimizing over use and unnecessary costs.

Measurement

The Applicant states that MRI results are and will continue to be a part of a "fully integrated medical record,"²⁶ for Winchester Hospital patients, through electronic medical records and a Picture Archiving Communication Systems (PACS).²⁷ These tools, the Applicant states, are currently used by Winchester Hospital and at Unicorn Park and will be used at the Satellite clinic on the WH campus. The Applicant asserts that the integrated medical record allows for more efficient work practices because primary care physicians and specialists have access to the same patient information in real-time, which enhances reaction time, clinical decision-making, care coordination and reduces the potential for duplication of services and unnecessary testing. The Applicant provided metrics on patient satisfaction, access and quality of care with measure specifications and projections. (Attachment 1) These metrics will become part of the annual reporting on the DoN project.

²² The HPC reported Original Medicare spending for imaging in Massachusetts totaled \$762.1 million in 2015. (<https://www.mass.gov/service-details/hpc-datapoints-issue-7-variation-in-imaging-spending>)

²³ The Health Policy Commission (HPC) reported that settings of care for services play a role in higher imaging spending with imaging performed at hospital outpatient departments (HOPDs) "costing substantially more than the same test performed in office settings or at freestanding imaging centers," when the HPC asserts, these tests can be performed safely and effectively in all of these settings. HPC DataPoints, Issue 7: Variation in Imaging Spending. (n.d.). Retrieved July, 2018, from https://www.mass.gov/service-details/hpc-datapoints-issue-7-variation-in-imaging-spending#!/vizhome/imaging_final/Annualimagingsspendingperbeneficiarybystate

²⁴ The Applicant states that this \$400 flat rate is a Medicare contracted rate whether the patient has Medicare or not. DoN Application 18042417-RE, Attachments, at page 12.

²⁵ The National Highway Traffic Safety Administration defines Inter-facility patient transfer as any transfer, after initial assessment and stabilization, from and to a health care facility and examples of inter-facility transport include hospital to hospital and clinic to hospital transfer. (https://www.ems.gov/pdf/advancing-emergency-systems/Provider-Resources/Interfacility_Transfers.pdf)

²⁶ DoN Application 18042417-RE, Attachments at page 18.

²⁷ Picture Archiving and Communication System (PACS) is a medical imaging technology that captures, stores, displays, and shares images from various medical imaging modalities such as MRI.

Community Engagement

Prior to submitting a DoN application, the DoN Regulation requires applicants to have engaged and consulted with the community.^{28,29} The Applicant presented on the proposed project at a Community Forum to engage community partners and local stakeholders and at a meeting of WH's Patient and Family Advisory Council (PFAC).³⁰ The Applicant posted the legal notice on the WH and Shields website to bring increased awareness about the project and to provide an opportunity for patients to comment on the project. The Applicant reported positive attendance and feedback from community partners and local stakeholders. DoN staff reviewed the slides and sign-in sheets of these meetings and found that in the context of factor 1 the Applicant met the community engagement standards in the planning phase of the Proposed Project. Staff has received no negative comment on this proposed project.

Factor 3

The Applicant has certified that it is in compliance and in 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

Under factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing patient panel. Documentation sufficient to make such finding must be supported by an analysis by an independent CPA. The Applicant submitted such an analysis performed by BDO USA, LLP (BDO) dated April 16, 2018 (CPA Report).

In order to assess the reasonableness of assumptions used in the preparation of projections, and the feasibility of the projections for the expansion of the MRI clinic through the addition of one 1.5T MRI unit, the CPA Report reflects a review and analysis of the Applicant's financial projections for fiscal years (FY) 2018 through 2023 and supporting documentation. BDO analyzed projected revenues for the three MRI units (2 at Unicorn Park, 1 at WH campus), as a function of the number of scans and rates per scan. BDO reported that the projected rate per scan in each year of Projections is within range or below the Applicant's historical rates per scan.

The addition of an MRI unit is projected to increase equipment maintenance expenses consistent with the other two units. Salaries associated with the staffing needs for the third MRI

²⁸ The Community Engagement Guide describes community engagement processes on a continuum from "Inform" and "Consult" through "Community driven-led." For the purposes of factor 1, engagement defines "community" as the Patient Panel, and requires that the minimum level of engagement for this step is "Consult."

²⁹ *Community Engagement Standards for Community Health Planning Guideline* (Rep.). (2017, January). Retrieved May, 2018, from Massachusetts Department of Public Health website:
<https://www.mass.gov/files/documents/2017/01/vr/guidelines-community-engagement.pdf>

³⁰ The Winchester Hospital (WH) Patient and Family Advisory Council (PFAC) was established in 2010. The WH PFAC consists of 15 members including patients, family members of patients, and hospital clinicians and administrators.

unit are consistent with current technologist salaries of the existing MRI units. BDO reported one-time start-up costs related to the proposed project and Community Health Initiative payments (CHI) which will result in an increase in certain expenses that BDO states will decrease as efficiencies due to economies of scale result in revenue from the third MRI. These estimated operating expenses were determined by BDO to be reasonable.

BDO, upon reviewing a preliminary proposal related to equipment cost, and the proposed financing of the project with projected interest and debt payments, determined that the proposed project “will be adequately financed and the Applicant will be able to sufficiently service its debt.”³¹ BDO reported that the projections exhibit a cumulative operating EBITDA surplus of 48.3%, which BDO found to be reasonable and based upon feasible financial assumptions. The CPA Report found that 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 Shields.”³²

Factor 5

Factor 5 requires the Applicant to “describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs and addressing, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes.”

The Applicant looked at the relative merit of the addition of another MRI unit at Unicorn Park which would address increasing volume and utilization but would not alleviate the need for the transport of WH inpatients and ED patients to Unicorn Park for MRI services, as well the associated risks and costs of such transport. The Applicant dismissed the addition of a unit at Unicorn Park because the benefits of providing co-located services at the WH main campus was a superior option for the provision of MRI services. The Applicant affirms that co-location of MRI services on WH’s main campus allows for more efficient and integrated care delivery, improves health outcomes and the patient care experience, and reduces healthcare expenditures.

Factor 6

Background

The Community Health Initiative (CHI) component of the DoN regulation requires approval of the Applicant's plans for fulfilling its responsibilities set out in the Department's Community-based Health Initiatives Guideline (Guideline).³³ This is a Tier 1 project, which applies to projects with a CHI contribution under \$500,000. The Applicant is required to, and did submit documentation showing that the existing community health needs assessment (CHNA) and community health improvement planning (CHIP) processes both evidence a sound community

³¹ DoN Application 18042417-RE, CPA Report, at page 11.

³² DoN Application 18042417-RE, CPA Report, at page 11.

³³ Determination of Need Community-Based Health Initiative Guideline, January 2017 available at <https://www.mass.gov/files/documents/2017/01/oa/guidelines-chi-planning.pdf>

engagement process and demonstrate an understanding of the DoN Health Priorities sufficient for selecting strategies to fund and implement following approval of the DoN project.

In making its recommendation to the Department, DPH staff may require corrective actions or steps to be taken based on the information provided by the Applicant which will become conditions of approval. DPH staff may also make recommendations that, while not conditions of approval will be kept as reference for subsequent DoN applications and/or are offered as opportunities for improvement relative to the Applicant's community engagement practices. Tier 1 projects are designed to utilize a hospital's existing community benefits structures subject to DPH staff requiring corrective actions only on those items deemed to be minimally necessary to meet community engagement expectations.

If the DoN is approved by the Department, the Applicant (then Holder of a DoN) will work with its Community Benefits Advisory Board or equivalent to complete any additional community engagement requirement and select Health Priority strategies for funding and implementation from the existing CHNA/CHIP. These processes, selection of the Health Priorities and funding decisions, are conditions of the DoN and enforceable as such.

This Application

In compliance with the requirements of the Guideline, and based on their own analysis, Winchester Hospital/Shields MRI, LLC submitted the following: a CHNA/CHIP Self-Assessment, 4 Stakeholder Assessments and the 2016 Winchester Hospital Community Health Needs Assessment (CHNA). Staff from DPH's Office of Community Health Planning and Engagement and one member of the cross-bureau Community Engagement Workgroup participated in reviewing these materials.

Summary CHI Review

1. Engagement levels by community health improvement planning stage
 - a. DPH agrees with the Applicant's Self-Assessment that the 2016 CHNA/CHIP does not meet minimum standards for engaging the community at large for several of the 5 stages of the CHNA/CHIP process. As this is a Tier 1 project, DPH notes that it is of primary importance to develop an understanding of the barriers that community members and community based organizations may experience in accessing the funding opportunity that this project will generate.
2. Advisory committee representation
 - a. The Advisory Committee is missing important sectoral representation, specifically housing, transportation and community health centers.
3. The 2016 Winchester Hospital CHNA provides useful and actionable information relative to the DPH Focus Issues. However, there is a lack of actionable information on the 6 DoN Health Priorities (social determinants of health).

4. The CHNA-CHIP Self-Assessment did not list any other hospital/health system or community-led community health needs assessment that Winchester Hospital is associated or involved with.
 - a. Opportunities for collaboration with overlapping health systems are noted as a recommendation for future practice.

After review, staff recommends certain Conditions to the DoN (set out below). In addition, staff makes a series of recommendations and observations based upon the fact that, in future DoN applications coming from this Applicant, DPH will refer back to the issues noted during this review.

CHI Recommendations and Observations

The Holder, in its development of future CHNA/CHIPs and in future DoN Applications, should consider the following:

1. The description of barriers to community participation noted in Appendix A of the Community Engagement for Community Health Planning Guideline and to develop plans for understanding and addressing barriers in the service region.
2. Review of the DoN Health Priority Guideline to fully understand how to incorporate an analysis of the social determinants of health into needs assessments, priority setting and strategy implementation.
3. An analysis of possible cross-health system collaborators when conducting Winchester Hospital's 2019 CHNA.

CHI Conditions to the DoN and Timeline

1. Of the total required CHI contribution of \$189,750, \$18,975 will be directed to the CHI Statewide Initiative and \$170,775 will be dedicated to local approaches to the DoN Health Priorities.
 - a. Within one month of the date of the Notice Of Determination of Need, the Holder must submit a check for \$18,975 to Health Resources in Action (the fiscal agent for the CHI Statewide Initiative) and must promptly notify DPH (CHI contact staff) when the payment has been made.
2. Within one month of the Notice of Determination of Need, the Holder will submit to the Department a summary analysis of barriers to participation in funding opportunities in the service region (see Appendix A of the Community Engagement Standards for Community Health Planning Guideline for information on common barriers) and actions to be taken to address those barriers.
3. Within one month of the Notice of Determination of Need, the Holder will submit to the Department a written notice and description of its actions relative to the following obligation:
 - a. The Holder will either:
 1. Recruit new members from the Housing, Transportation and Community Health Center sectors for the Community Benefits Advisory Committee; or

2. Conduct key informant interviews with representatives from the Housing, Transportation and Community Health Center sectors to inform the funding plan.
4. The Applicant will comply with all future reporting requirements related to CHI as determined by DPH.
5. For this DoN CHI, the Applicant and the Department have agreed to certain post PHC approval steps and a timeline as spelled out in the CHI Planning Guideline:
 - The Applicant will select Health Priority Strategies, after reviewing the strategy selection criteria in the DoN Health Priority Guideline, from the 2016 Winchester Hospital Community Health Needs Assessment, in consultation with the community benefits advisory board (after taking action as required in condition #3).
 - Within 3 months of the Notice of Approval, the Applicant shall publicly post the funding plan to allow for public comment, or shall conduct a public request for proposal (RFP) process. If conducting a RFP process, the Applicant shall publicly release the RFP within 3 months of receipt of a duly-approved Notice of Determination of Need. If the Applicant is using a funding method other than a RFP they must notify DPH what those plans are within one-month of the Notice of Approval.

Finding and Recommendation

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 factors 1 and 2, 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, and add to the Commonwealth’s goals for cost containment, delivery system transformation and improved outcomes.

The Applicant provided evidence to support its assertion that the addition of one MRI unit at a satellite clinic on WH’s campus will; eliminate the need to transport patients, with the attendant costs and safety risks; create more integrated care for WH inpatients and ED patients by allowing them to receive all of their care on the WH campus; and alleviate capacity constraints improving access to convenient and timely MRI services WH for outpatients. The Applicant maintains that the resulting increase in access to high-quality MRI services for its patient panel will improve health outcomes, quality of life, and patient satisfaction in a cost-effective and efficient manner, which supports the Applicant’s compliance with Factors 1 and 2.

In addition, the Applicant is in compliance with factor 3. Based upon the CPA analysis, the Proposed Project is financially feasible in the context of factor 4. Expansion of an existing clinic to provide MRI services on the WH campus is, on balance, the superior alternative for meeting the existing Patient Panel needs from the perspective of quality, efficiency, and operating costs as required by factor 5. Finally, the Applicant is in compliance with the requirements of the CHI

planning process for the purposes of factor 6, subject to the CHI Conditions and Timeline and pursuant to 105 CMR 100.310(J).

Based upon a review of the materials submitted, Staff finds that the Applicant has met each DoN factor and recommends that the Department approve this Determination of Need application for expansion of its Satellite clinic through the addition of a 1.5T MRI unit subject to all standard conditions (105 CMR 100.310).

In compliance with the provisions of 105 CMR 100.310(L) and (Q), 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 project, the Holder shall address its assertions with respect to the cost benefits of co-location of an on-campus MRI unit as well as the metrics provided in Attachment 1.

Attachment 1

Assessing the impact of the proposed project

The Applicant developed the following quality metrics and reporting schematic that will measure patient satisfaction, access and quality of care.

1. **Patient Satisfaction:** Patients that are satisfied with care are more likely to seek additional treatment when necessary. The Applicant will review patient satisfaction levels with the MRI service.

Measure: To ensure a service-excellence approach, patient satisfaction surveys will be distributed to all patients receiving MR imaging services with specific questions around: (a) satisfaction with the wait time for services; (b) satisfaction around the comfort of procedures; (c) satisfaction levels with pre- and post-appointment communication; and (d) satisfaction with staff and facility environment.

Projections: Baseline: 90% Year 1: 90% Year 2: 91% Year 3: 92%

Monitoring: Any category receiving a less than exceptional rating (satisfactory level) will be evaluated and policy changes instituted.

2. **Quality of Care - Critical Value Reporting:** When critical values or abnormal test results are registered within an electronic medical record for a patient, the referring physician is notified via phone call from the WH reading radiologist. Subsequently, the critical values/abnormal results are dictated into the WH PACS system and the report is sent electronically to the referring physician. This report is also sent to the Applicant, so that it is in the electronic medical record of both the Hospital and the Applicant. A benefit of having an integrated electronic medical record and PACS system is the ability to send these messages to a referring physician, so that clinical decisions may be expedited.

Measure: Number of contracted radiologists conducting critical value reporting on cases being interpreted.

Projections: Baseline: 100% Year 1: 100% Year 2: 100% Year 3: 100%

Monitoring: MRI scans will be forwarded to the WH film library and follow-up will be conducted to the referring physician. The radiologist will be made available to answer any questions.

3. **Quality of Care - Quality of MRI Scan:** The quality of an MRI scan is imperative to its interpretation. Accordingly, the Applicant will evaluate the number of scans that need to be repeated within a 48-hour period from the date of the original scan to ensure radiology technicians are performing appropriate scans.

Measure: The number of repeat MRI scans performed on patients within a 48-hour period from the date of the original scan.

Projections: Baseline: <1% Year 1: <1% Year 2: <1% Year 3: <1%

Monitoring: MRI technologists will track the number of scans that are repeated and scheduled for the next scan day. Technologists will document each case and conduct a monthly comparison to total volume to meet or exceed the metric.

4. **Quality of Care - Peer Review Over Read Correlation:** To evaluate the accuracy of scan interpretations, the Applicant will conduct peer review readings to ensure quality outcomes for patients.

Measure: The Applicant will have contracted radiologists conduct peer review readings on a random basis based on the American College of Radiology ("ACR") Peer to Peer criteria and will follow-up on all discrepancies with the original reading radiologist.

Projections: Baseline: 95% Year 1: 95% Year 2: 96% Year 3: 97%

Monitoring: A random selection of cases based on ACR Peer to Peer criteria will be reviewed. Radiologists will evaluate scans documenting any inconsistencies and discuss outstanding issues with the original reading radiologist.

5. **Access - Backlog Reporting:** The Proposed Project seeks to ensure access to MRI services. Accordingly, the Applicant will track any backlogs associated with the service.

Measure: The number of times scanning day utilization is greater than 90% and adjustments need to be made to the schedule.

Projections: Baseline: <10% Year 1: <10% Year 2: <10% Year 3: <8%

Monitoring: Applicant's staff will assess daily hours of service and implement adjustments if necessary.

6. **Provider Satisfaction - Value Assessment:** Ensuring provider satisfaction with MRI scans and their overall value when treating patients is necessary to assess the impact on care for patients. The Applicant will survey referring physicians to validate scan utility.

Measure: Confirmation with referral physician about the utility of MRI scans.

Projections: Baseline: 95% Year 1: 95% Year 2: 96% Year 3: 97%

Monitoring: MRI referral physician population will be queried to validate scan utility via surveys.