Introduction

The purpose of this supplement is to provide more specific information related to the locations of proposed services included in our Determination of Need (DON) application, including:

- More specificity as to which services will be located at which sites
- Which services are "new" vs. which services are "expanded"
- How the proposed services relate to non-DON physician office services that will be located adjacent to hospital services
- Additional detail regarding specific clinical programs, needs, and objectives

<u>Sites</u>

As outlined in our application, there are three sites included in our proposal:

- The Waltham location requires renovation and equipping space within the Hospital's existing facility at 9 Hope Avenue, Waltham, MA 02453 – this is ongoing renovation of an existing hospital licensed satellite
- The Weymouth location is a leased space to fit out and equip hospital licensed space located at 200 Libbey Parkway in Weymouth, MA 02188 – this is a relocation of physician office practices with wrap around supportive hospital services
- The Needham location requires land acquisition, construction, fit-out, and equipping space zoned for pediatric medical use at 380 First Avenue in Needham, MA 02492 – this is a new pediatric facility that will include both physician office space and hospital based services

<u>Services Provided at Each Site</u>

Much of the pediatric specialty care delivered by Boston Children's Hospital affiliated physicians occurs in their physician office which is a separate medical office setting from the hospital use space. These medical offices are considered either surgical (example Surgery or Orthopedics) or medical (example Pediatrics or Neurology). Many of the medical offices also have subspecialties with in them (example Gastroenterology is a Division of Pediatrics).

We have organized our delivery system in this manner in order to provide improved care for children while reducing overall costs. Because these visits are billed as physician office services, they do not include hospital outpatient department facility fees, and the co-payments or cost-sharing obligations for patients are reduced. This organizational structure also enables the medical offices to adjust their service delivery in flexible ways to best meet patient needs. For example, it has enabled the thoughtful development of multispecialty programs designed to meet the needs of medically complex children.

These medical offices in turn depend to a significant degree on hospital based services like phlebotomy, occupational therapy, physical therapy and imaging. Each of the locations included in our proposal includes both a medical office component and a separate hospital service component.

Categorization of hospital services

The hospital services outlined in the following table and the descriptive text below can be broadly broken down into four categories (and we have organized the discussion accordingly):

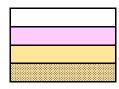
- 1. Wrap around services (e.g., phlebotomy, PT/OT, other testing like audiology, visual functions, pulmonary functions, echocardiograms, etc.).
- 2. Imaging
- 3. Surgical care (operating rooms, PACUs, etc.)
- 4. Specialized programs including behavioral health, sleep and infusion

In the table below, the "X" indicates whether a service is available at a given site. There are separate tables for hospital and medical office services. We have color-coded specific services to indicate whether they are existing, expanded, or new services. Of note, in many cases, the he Proposed Project is relocating existing capacity (e.g., from the Longwood campus or from another satellite) rather than simply adding capacity (more fully described in the discussion below related to specific services).

Legend:

Existing Services Expanding Services New Services

New Services Opened Within Last 6 Months



Waltham	Needham	Weymouth
the DoN		
Services Provided By Boston Children's Hospital under		

Behavioral Health Services

Community Based Acute Treatment Med/Psych Day Program 12 Bed Inpatient Unit

X		
X		
Х		

All Other Diagnostic & Therapeutic Services

Phlebotomy
Plaster Room/Casting
Audiology
Speech Therapy
Vestibular Lab
Nutrition
Echocardiograms
Cardiac Stress Tests
Visual Functions/Testing
Urodynamics Lab
Breath Testing
Pulmonary Lab
Physical Therapy/Occupational Therapy
Sleep
Infusion
Pharmacy

X	X	X
X	X	X
X		X
X		X
X		
X	X	X
Х		X
X		X
Х	Х	X
X		
X	X	X
X		X
X	X	X
X	Α	A
X		
X	V	
^	Х	

Peri-Operative Services

Operating Rooms
Inpatient Surgical Beds

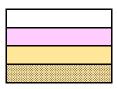
X	Х
X	

<u>Radiology</u>

Diagnostic	X	X	Х
Fluoro	X	X	X
Ultrasound	X	X	X
СТ	Х		
MRI	X	X	X
Interventional Radiology		X	

Legend:

Existing Services
Expanding Services
New Services
New Services Opened Within Last 6 Months



	Services Provided By Boston Children's Physician Office		
	Practices		
	Waltham	Needham	Weymouth
	Mix of	GI & Nurtion	Mix of
Medical Subspecialties (Endocrinology, Derm,	Subspecialty	Office Based &	Subspecialty
GI/Nutrition, Immunology, Pulmonary)	Office Based	Surgical	Office Based
	Office Based &	Office Based &	
Anesthesia including Pain Management	Surgical	Surgical	
Cardiology	Office Based		Office Based
Dental	Surgery Only	Surgery Only	
Neurology	Office Based		Office Based
Neurosurgery	Office Based		
		Office Based &	
Ophthalmology	Office Based	Surgical	Office Based
	Office Based &	Office Based &	
Orthopedic Surgery / Sports Medicine	Surgical	Surgical	Office Based
	Office Based &	Office Based &	
Otolaryngology	Surgical	Surgical	Office Based
	Office Based &		
Plastic Surgery/Oral Maxial Facial Surgery	Surgical		Office Based
Psychiatry	Office Based		Office Based
	Office Based &		
Surgery	Surgical	Surgery Only	
	Office Based &		
Urology	Surgical	Surgery Only	Office Based

Discussion: DoN Rationale

The care of pediatric patients differs from that of adult patients. Children's hospitals are uniquely capable of providing the widest range of pediatric services, including care for children with medical complexity and children with rare conditions. 1 As the region's solely dedicated pediatric hospital, Boston Children's provides a full continuum of pediatric care across all disease types. Timely intervention and ongoing supportive care help children become the healthiest adults they can be. Pediatric specialty care is decreasing in availability in community hospitals, a trend that has not applied to academic medical centers.^{2,3} Pediatric care continues to transition certain services from inpatient based to outpatient or physician office settings.^{4,5} Transitioning of care safely to outpatient settings is less disruptive to the patient and family. For example, in 2019, 48.1% of Boston Children's care was provided in outpatient settings. While the setting of care continues to shift to outpatient, the need for wrap around services (e.g., phlebotomy, imaging, and other specialized diagnostic and therapeutic services) are required to provide the necessary care. Last, clustering of pediatric volume to achieve economies of scale in the use of specialized medical equipment for different body types and management of pediatric trained professionals (phlebotomists, technologists, etc.) contribute to cost control. As the COVID-19 pandemic demonstrated that capacity constraints continue to challenge pediatric care in Massachusetts, Boston Children's looks to expand access to patients who currently cannot access needed services in a timely fashion.

As reported by the American Academy of Pediatrics, 21.1% of children in the Commonwealth have special health care needs. Many of the children and families referred to Boston Children's are living with multiple chronic conditions. Managing that medical complexity through specialized and interdisciplinary pediatric care teams is vital to maintaining and improving health outcomes and quality of life. BCH affiliated pediatric subspecialists will provide care at each of the Proposed Project sites. The mix and size of each subspecialty

¹ Berry, J.G., Hall, M., Neff, J., Goodman, D., Cohen, E., ... Feudtner, C. (2014). Children with Medical Complexity and Medicaid: Spending and Cost Savings. *Health Affairs*, 32(12). https://doi.org/10.1377/hlthaff.2014.0828.

² Franca, U.L. and McManus, M.L. (2017). "Availability of Definitive Hospital Care for Children." *JAMA Pediatr.*, 171(9). https://doi.org/10.1001/jamapediatrics.2017.1096.

³ Franca, U.L. and McManus, M.L. (2018). "Trends in Regionalization of Hospital Care for Common Pediatric Conditions." *Pediatrics*, 141(1). https://doi.org/10.1542/peds.2017-1940.

⁴ Liptak, G.S., Burns, C.M. and Davidson, P.W. (1998). "Effects of Providing Comprehensive Ambulatory Services to Children with Chronic Conditions." *Archives of Pediatrics and Adolescent Medicine*, 152(10):1003-1008. https://doi.org/10.1001/archpedi.152.10.1003.

⁵ Glied, S. and Cuellar, A.E. (2003). "Trends and Issues in Child and Adolescent Mental Health." *Health Affairs*, 22(5). https://doi.org/10.1377/hlthaff.22.5.39.

⁶ See Pediatric Subspecialty Shortages Fact Sheets, American Academy of Pediatrics, https://downloads.aap.org/AAP/PDF/Advocacy/Massachusetts SubspecialtyFactSheet.pdf

service has been determined based on the care that can be safely and effectively provided closer to where patients reside. These subspecialty services include Cardiology, Gastroenterology & Nutritional Care, Neurology, Ophthalmology, Orthopedic Surgery/Sports Medicine, Otolaryngology, Pain Management, Plastic Surgery, Pediatric Subspecialty (Endocrinology, Immunology, Pulmonary, etc.), Psychiatry, Surgery and Urology.

The placement of specialized services in certain locations has been quite deliberate to ensure the delivery of care safely and allows Boston Children's Hospital to leverage existing resources in the provision of that care. For example, our existing Waltham campus has services that run 24/7 requiring medical coverage and infrastructure resources such as security and food amenities. The expansion of our sleep service at that location eliminates the need to replicate those resources. Similarly, the delivery of infusion services requires a safety net of resources (code teams, et al) to respond should an emergency arise. Expansion of infusion at the Waltham location leverages the current set of response teams.

Discussion: Geographic Access

Boston Children's Hospital and its affiliated physicians have a coordinated strategy that deploys highly specialized professionals throughout the Commonwealth. While our three proposed locations are all located in HSA 4, each will serve patients from across the state. The Proposed Project addresses the needs of pediatric patients in ways that can only be delivered by a dedicated pediatric integrated health system. The clinical services distributed at each location are optimized to ensure access to integrated and coordinated services. The locations are sited along major highways and are highly accessible to pediatric population in underserved areas.

For Mass Health enrolled patients who do not have access to public or private transportation to their medical appointment, the PT-1 program is available to provide rides to and from an appointment. Boston Children's Hospital social workers are staffed at every location and support patients who need to use the program (a medical provider must request a ride on behalf of a patient). In recognition of the importance of transportation access as a factor in the health and wellbeing of children, Boston Children's Hospital staff has worked closely with Mass Health to find ways to enhance the effectiveness of the PT-1 program, both to improve the efficiency of the application process for providers and to address user experience issues unique to families.

Wrap Around Services

The delivery of subspecialty care often relies on the availability of wrap around services that aid the providers in determining the diagnosis and development of a treatment plan. Certain wrap around services as outlined in the attached chart are present at each location in order to

support the timely coordination of care. For example, each location will have phlebotomy and PT/OT services. On average 17% of all ambulatory visits require phlebotomy. Furthermore, for children with medically complex conditions that require frequent testing of blood (i.e., diabetes), the availability of walk in phlebotomy sites in the community increases the likelihood of such testing, and therefore drives better outcomes while providing families and patients easier access to such services.

Physical therapy services provided improve movement, range of motion, strength, muscle tone, coordination, balance, gait and functional ability with the goal of maximizing each patient's function and independence in all areas of their life, including at home, in school, and in their community. The physical therapy team works closely with physicians, nurses, patient care coordinators and others within and outside of the Boston Children's Hospital system to achieve this goal. The physical therapy staff works with a variety of diagnoses including musculoskeletal, neurologic and orthopedic disorders; sports injury management; gait disorders; balance and coordination deficits; movement disorders; congenital conditions; infant torticollis and plagiocephaly; delayed gross motor development; posture deviations, and equipment and seating needs. Provision of physical therapy services to children with chronic or congenital conditions can maximize functional potential over the course of a life time. The occupational therapy services provided are aimed at helping the patients to maximize functional independence and participation in all occupations, across several environments (e.g. home, work, school, community). Occupational therapists work with the patient and caregivers to help regain and/or develop the skills necessary for the highest level of functions and independence.

Finally, individual subspecialties may rely on hospital-based testing services requiring specialized equipment and these services will be available at sites providing that care. The availability of visual function testing that relies on specifically designed rooms with highly specialized equipment is needed in order to inform a treatment plan by pediatric ophthalmologists. Audiology testing requires child friendly environment in order to ensure that the young children can participate in studies to determine hearing loss. Pediatric trained audiologists work closely with parents to ensure that accurate test result is provided as part of the overall care plan.

Radiology, MRI and Imaging

Most of the subspecialty services rely on radiology services (diagnostic, fluoroscopy, ultrasound, and interventional radiology) as part of their diagnosis and treatment plan. An integrated collaborative care model between radiologists and subspecialists for the treatment of children with unique care needs is essential. Pediatric imaging protocols for studies such as diagnostic radiography, CT, and fluoroscopy ensure that the radiation dose is optimized for the

size of the child and the indication for exam. This approach is especially important for children with complex or chronic conditions who may require serial imaging over time. Ensuring that continuous, consistent imaging record is accessible in the patient's medical record is essential to supplementing the request for an exam to ensure that the study meets the clinical need. Understanding the patient's symptoms, clinical concerns to be addressed and treatment history influence how an exam is protocoled, performed and interpreted. An intact and consistent imaging record is also important for children undergoing serial exams as a comparison to prior exams and is critical to understanding the effects of treatment or the progression of disease over time. Subspecialty exam supervision and interpretation improves the alignment between the imaging and clinical specialties leading to a greater likelihood that the imaging addresses the specific clinical concern (for example pediatric urology or pediatric neuroimaging). The approach of utilizing highly subspecialized pediatric imagers has the potential to decrease the time to diagnosis, avoid additional testing and associated costs and improve outcomes. Approximately 1 in 5 visits across our subspecialty practices requires an imaging service.

There are limited dedicated pediatric MRI options in the community outside of those at existing Hospital satellite locations, and the Department of Radiology at Boston Children's Hospital is the primary source of pediatric imaging specialists and subspecialists in the Commonwealth. Thus, pediatric patients in need of MRI have to choose whether to undergo imaging at adult-focused facilities which may be closer and more accessible to them, or traveling for an exam at an existing Hospital location. The current wait time for a sedated MRI is over 4 weeks. Expanding capacity to non-sedated studies in the community will allow these patients to access testing closer to home while improving access to sedated MRIs on Longwood Avenue. The Proposed Project will add two MRI units in HSA 4. Siting the proposed MRI units at the Weymouth Facility and the Needham Facility will enhance access to pediatric-focused MRIs in the community and satisfy existing and future Patient Panel needs.

Pediatric-focused MRI has become a central tool in diagnosis, surgical management, and treatment efficacy assessment for a large number of conditions across much of the pediatric disease spectrum. Over the last several years, Boston Children's Hospital has made a concerted effort to transition pediatric scanning away from modalities that use ionizing radiation (e.g. computerized tomography ("CT") scans) towards those that do not (e.g. MRIs). For example, clinical indications that have shifted towards MRI include imaging of children with new onset of seizures, newborns in need of neuroimaging, imaging of children with IBD, and imaging of children with appendicitis. For children in particular, this shift reduces their lifetime dose of ionizing radiation. The deployment of 3T MRI units allow for faster scans and higher image resolution than more commonly used machines in the community.

The MRI needs of pediatric patients are unique: MRI coils designed to fit smaller bodies and bodies of different body shapes and locations across a range of patients from infants to adult-sized adolescents; customized motion-correction software that compensates for pediatric patients unable to stay still; availability of behavioral health staff able to manage the needs of children with behavioral health challenges. Through this specialized equipment and pediatric tailored protocols, the Hospital can reduce the need for anesthesia and avoid the need for repeat studies. For example, in an internal review of repeat imaging studies, the Hospital found that 84% of pediatric patients who received an MRI for epilepsy in the community needed to have a repeat MRI prior to assessment and treatment at the Hospital due to the outside exam providing insufficient detail to assess for a potentially surgically treatable lesion. Given the significant variation in conditions, including congenital conditions, present for pediatric patients as compared to adult patients, and the unique challenges to interpreting MRI scans for pediatric patients, higher resolution imaging and specialized radiology training are necessary.

Ambulatory Surgery

The day surgery programs planned for the Waltham Facility and the Needham Facility are part of a single coordinated plan to better address the unique surgical needs of pediatric patients. The Proposed Project is relocating existing capacity rather than simply adding capacity. For example, the Hospital intends to consolidate day surgery volume at the Waltham Facility and Needham Facility and reduce day surgeries at its Lexington location, resulting in a net increase of four ORs. More generally, Boston Children's Hospital seeks to transition less acute pediatric specialty care and day surgery from the capacity-constrained Longwood campus to community locations that are less costly to operate and more accessible to patients. In 2019, approximately 88% of day surgery visits were by patients residing outside of Boston. The Waltham Facility and the Needham Facility will thus increase accessibility for Metro West HSA patients, but also for patients residing in the surrounding HSA regions given the locations along major transportation corridors.

Pediatric surgical care is different from adult care in meaningful ways, *i.e.* differences in body size and shape, mental and behavioral abilities, and dependence on family and caregivers. As noted in the Bailit report, pediatric patients require special operating rooms with the right equipment and personnel to ensure safety and quality. The American Society of Anesthesiologists and Society of Pediatric Anesthesia issued separate statements that highlight the importance of proper categorization of pediatric surgical procedures, an annual minimum case volume for pediatric anesthesiologists to maintain clinical competence, specialized policies for pediatric pain treatment, pediatric surgical equipment and drugs and the availability of

pediatric-specific operating rooms, post-anesthesia care units and intensive care units.^{7,8} Children do not always need to visit a Level I surgical center to receive the services they need, especially given that these facilities are harder for families and their support networks to access. The American College of Surgeons' highlights the importance of ambulatory surgical centers in providing an accessible, appropriate outpatient treatment option for children in its "Optimal Resources for Children's Surgical Care" document.⁹ In addition, pediatric-focused ambulatory surgical centers associated with more intensive hospital-based programs have been an important contributor to expanded access at a lower cost than similar services accessed at university-based hospital facilities.¹⁰ Expanding the availability of pediatric operating rooms within a children's facility, like Boston Children's, therefore is a valuable, cost-effective way to improve access to surgical care.

The role of specifically trained pediatric anesthesiologists within the surgical program in determining the type of anesthesia impacts the post-acute treatment of the patient. Pediatric regional anesthesia—i.e., selective "blocking" or numbing of extremities, whole body parts or body zones—that allows surgery to proceed without a general anesthetic, reduces opiate exposure, and increases surgical efficiency. In addition, these pediatric specialists utilize pain management techniques such as sending patients home with indwelling regional catheters that continually infuse local anesthetic drugs, converting two- to three-day inpatient stays into day surgeries that can be performed in the community. Continued innovation is expected to allow more surgical cases to be handled as day surgeries.

Specialized Programs

a. Sleep Services

Sleep disorders are common in children and the most common conditions are obstructive sleep apnea, childhood insomnia, excessive daytime sleepiness, restless sleep disorder, and narcolepsy. Sleep apnea is estimated to affect 3-5% of children, with higher prevalence in racial minorities. Although the American Academy of Pediatrics recommends an in lab overnight sleep study as the "gold standard" for the diagnosis of obstructive sleep apnea in children, it is estimated that only about 10% of children with clinical symptoms undergo the optimal

⁷ American Society of Anesthesiologists. (2016). "Statement on Practice Recommendations for Pediatric Anesthesia." Retrieved from https://www.asahq.org/standards-and-guidelines/statement-on-practice-recommendations-for-pediatric-anesthesia.

⁸ Society for Pediatric Anesthesia. "Policy Statement on Provision of Pediatric Anesthesia Care." Retrieved from https://pedsanesthesia.org/about/provision-of-pediatric-anesthesia-care/.

⁹ American College of Surgeons. (2015). "Optimal Resources for Children's Surgical Care." Retrieved from https://www.facs.org/-/media/files/quality-programs/csv/acs-csv_standardsmanual.ashx.

¹⁰ Fabricant, P.D., Seeley, M.A., Rozell, J.C., Fieldston, E. (2018). "Cost Savings from Utilization of a

Pediatric Ambulatory Surgery Center for Orthopaedic Day Surgery." *Pediatrics*, 141(1) 616. https://doi.org/10.1542/peds.141.1_MeetingAbstract.616.

diagnostic testing. Expansion of our bed capacity to conduct these tests will significantly improve the quality of and access to care for children in the Commonwealth.

Sleep apnea seen in neonates and can present with apnea and desaturations, these infants are at high risk for sudden infant death. In addition, sleep disorders are commonly seen in children with complex disorders such as asthma, cystic fibrosis, children with tracheostomies and congenital heart disease. It is also commonly seen in children with autism and ADHD. Under diagnosis of sleep disorders in children impacts their quality of life and long-term neurocognitive outcomes. Throughout the COVID pandemic, cases of insomnia and other sleep disorders have skyrocketed among children, emphasizing the need for our services to be readily available. The current wait list for a sleep study is approximately two and a half months. Expanding the clinical services ensures that talented and highly specialized physicians are able to meet the huge patient demand and backlog. The Proposed Project will facilitate expansion of pediatric sleep services for the only pediatric sleep program in New England, addressing the need for a child in the Commonwealth to drive as far as 94 miles for sleep medicine care as reported by the American Academy of Pediatrics.¹¹

b. Behavioral Health Services

The Commonwealth has been facing a long-term and well-known crisis in pediatric behavioral health, significantly exacerbated by the COVID-19 pandemic. The COVID-19 pandemic has resulted in greater need for access to inpatient adolescent and pediatric psychiatric services due to quarantine orders, remote learning and destabilization of families. Compared with 2019, the proportion of mental health-related visits for children aged 5-11 and 12-17 years increased approximately 24% and 31%, respectively.

To meet this need, BCH also operates clinically integrated programs in multiple locations and across the continuum of care, from inpatient psychiatric and psychiatric emergency care, to community-based acute treatment ("CBAT"), outpatient programs, and school-based programs and supports. In particular, BCH received a Determination of Need approval earlier this

¹¹ See Pediatric Subspecialty Shortages Fact Sheets, American Academy of Pediatrics, https://downloads.aap.org/AAP/PDF/Advocacy/Massachusetts_SubspecialtyFactSheet.pdf

¹² See Karen Dineen Wagner, MD, PhD, New Findings About Children's Mental Health During COVID-19, Psychiatric Times (October 7, 2020), https://www.psychiatrictimes.com/view/newfindings-children-mental-health-covid-19.

¹³ See Leeb RT, Bitsko RH, Radhakrishnan L, Martinez P, Njai R, Holland KM. Mental Health- Related Emergency Department Visits Among Children Aged < 18 Years During the COVID-19 Pandemic - United States, January 1-0ctober 17, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1675-1680. DOI: http://dx.doi.org/10.15585/mmwr.mm6945a3external icon.

calendar year to add a new 12-bed inpatient adolescent and pediatric psychiatric unit, which will be opening on October 4, 2021.¹⁴

To further meet the needs of patients and families, the Proposed Project will allow the Hospital to add a med-psych partial hospitalization program at the Waltham Facility. The program will provide pediatric patients with intensive behavioral health services during the day and allow patients to return home in the evening, enhancing the Applicant's continuum of care for behavioral health.

Through the Proposed Project, the Hospital will continue to implement its coordinated and integrated care models. It will co-locate multi-disciplinary services, including through integration of behavioral health services throughout departments. It is also intended to increase the availability of same-day coordinated care in the community, and improve the ability of families to schedule multiple appointments with care team members on the same day at the same location (also helping to reduce missed school days). Multidisciplinary care for children with chronic conditions such as obesity, inflammatory bowel disease, pain management, and aero digestive disorders, as well as behavioral challenges, is becoming the standard of care across the country. At Boston Children's, we utilize teams of physicians, psychologists, nurses, social workers, and dietitians to provide comprehensive care.

c. Infusion Services

Infusion therapy is administered to infants, children and adolescents who require either one-time or ongoing IV therapy for a variety of acute and chronic illnesses including cancer, blood or genetic disorders, gastrointestinal and endocrine disorders. Ambulatory infusion programs are an alternative to inpatient admission and Emergency Room visits for patients requiring infusion therapies and novel medical day treatments. Registered nurses and nurse practitioners are able to administer complex medical therapies safely and efficiently in our outpatient family-centered environment, 7 days/week, offering both day and evening hours. Throughout the pandemic and as our Emergency Department and Inpatient Units face extraordinary capacity challenges, the need for outpatient infusion services and day treatment models of care has become critical for our patients whose health and well-being depend on consistent access to therapies/procedures/services including blood products, biologics, and Monoclonal Antibody infusions for COVID-19. Children diagnosed with immunodeficiency disease, IBD, sickle cell, diabetes, and other chronic diseases require easy access to infusion services often on a weekly basis for life. Treatment times will vary, from as little as 15 minutes up to eight hours.

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¹⁴ See Determination of Need Approval Related to COVID-19 Letter from Lara Szent-Gyorgyi to Donna Casey dated January 15, 2021.