

**STAFF REPORT TO THE PUBLIC COUNCIL
FOR THE DETERMINATION OF NEED**

DoN Project Number	17040515-RE
Applicant Name	Henry M. Goldman School of Dental Medicine (GSDM)
Applicant Address	100 East Newton Street Boston, MA 02118
Date Received	July 31, 2017
Type of DoN Application	Capital Expenditure
Maximum Capital Expenditure (MCE)	\$37,076,692.00
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	\$1,853,834.60 (to statewide fund)
Staff Recommendation	Approval with conditions
Public Health Council (PHC) Meeting Date	November 8, 2017

PROJECT SUMMARY AND REGULATORY REVIEW

The Henry M. Goldman School of Dental Medicine (GSDM) submitted a Determination of Need (DoN) application for a Substantial Capital Expenditure pursuant to M.G.L. c.111, §25C and the regulations and guidelines adopted thereunder for new construction of 13,717 gross square feet (GSF) and renovation of 19,767 GSF of its licensed dental clinic (Clinic). The total requested GSF is 33,484. The proposed project includes the addition of six dental chairs and one cone beam computed tomography (CBCT) machine.

Applications for substantial capital expenditures are reviewed under the DoN regulation at 105 CMR 100.000. Under the regulation, 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. There are six factors set forth in the regulation. This staff report addresses each of the six factors in turn.

The Department received no public comment on the application.

BACKGROUND INFORMATION

The Henry M. Goldman School of Dental Medicine (GSDM) is one of 17 schools and colleges in the Boston University system. The GSDM, located on Boston University's Medical Campus, has 700 students and a faculty of 325 educators, clinicians, and researchers. The GSDM offers seven pre-doctoral and postdoctoral degrees and certificates of advanced graduate study. The Doctor of Dental Medicine (DMD) degree is a four-year program at GSDM.

The Pre-Doctoral Treatment Center (the Clinic) that is the subject of this proposed project is a clinic licensed by the Department of Public Health pursuant to M.G.L. c. 111, §51. At the Clinic, care is provided by students enrolled in the DMD program, under the supervision of licensed faculty members. GSDM has required students to learn through this clinical care model as part of the DMD degree since 1972. Each year, approximately 300 GSDM DMD candidates provide general and restorative dental care, including examinations and diagnostic imaging, in the Clinic under faculty guidance and supervision.

Over the course of an eight-year strategic planning process, the Applicant determined that the GSDM and the Clinic were housed in an inefficient facility, "at the end of its lifecycle." The Applicant states that critical facility issues impede student education and affect patient care in the Clinic. The current 44 year old facility requires renovation and construction to support the programmatic improvements to both student education and patient care that have occurred since its construction in 1973. The proposed project would bring the facility in line with current standards for dental care and create a physical environment that supports enhanced coordination and efficient delivery of care.

The following project goals for the Clinic were established based on their potential to positively impact both the education of students and the provision of dental care:

1. Provision of safe and high-quality dental care in the Clinic;
2. Implementation of Integrated Healthcare Teams;
3. Implementation of the Group Practice Model;
4. Co-location of all general dentistry services; and
5. Well-functioning facility.

Applications for capital expenditures are reviewed under the DoN regulation at 105 CMR 100.100. Under the regulation, 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 of the six Determination of Need Factors set forth within 105 CMR 100.210. This staff report addresses each of the six factors in turn.

ANALYSIS

Factors 1 and 2

Factor 1 of the DoN regulation requires that the Applicant address patient panel need, and demonstrate that the 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. Under factor 2 of the regulation, the Applicant must demonstrate that the project will meaningfully contribute to the Commonwealth's goals for cost containment, improved public health outcomes, and delivery system transformation.

Patient panel for the purposes of DoN is defined as, "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."¹ The Applicant reports that approximately 50,000 patients were seen in the Clinic over the past 36 months, and anticipates no changes to the volume of patients seen at the Clinic resulting from this project.

The Applicant asserts and research has shown that affordability is a barrier to accessing dental care.² The Clinic accepts all patients without regard to source of payment. The Applicant states that the fees for most of the offered dental services are in the lower half of the range of charges for comparable services throughout the Commonwealth. The payer mix of the patient panel is self-pay (59.98%), MassHealth (34.6%), commercial insurance (2.34%), Ryan White (1.93%), and Medicare (1.08%). For those dental services that are not covered by MassHealth, the Boston University MassHealth Patient Upgrade Program (BUMP UP) program provides basic restorative services at the lowest possible price for those MassHealth patients with some ability to pay.³ ⁴ These charges are reflected in the self-pay portion of payer mix.

Chronic Disease Management

Renovation of the clinic allows for inter-professional education to address the association between underlying chronic illnesses and their negative impact on oral health. Almost one-half (47%) of the patient panel reported at least one chronic condition. Generally, common risk

¹ United States, Massachusetts Department of Public Health, Determination of Need. (2017, January). *Determination of Need Regulation 105 CMR 100.100*. Retrieved September, 2017, from <http://www.mass.gov/courts/docs/lawlib/104-105cmr/105cmr100.pdf>

² N. R., & Auerbach, D. (2016, August 1). *Oral health care access and emergency department utilization for avoidable oral health conditions in Massachusetts* (Issue brief). Retrieved September, 2017, from Health Policy Commission website: <http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/oral-health-policy-brief.pdf>

³ B. (n.d.). GSDM Responds to MassHealth Cuts with Revamped BUMP UP. Retrieved October 3, 2017, from <http://www.bumc.bu.edu/2010/06/21/gsdm-responds-to-masshealth-cuts-with-revamped-bump-up/>

⁴ B. (n.d.). BUMP UP Program (MassHealth). Retrieved October, 2017, from <https://www.bu.edu/dental/patients/finance/bumpup/>

factors for oral disease and non-communicable chronic disease include sugar consumption, tobacco use, and alcohol. These risk factors undermine defenses against chronic infection in the mouth.^{5 6} The following table lists the reported chronic disease and behavioral risk factors documented in the Clinic's patient panel.

Chronic Disease		Behavioral Risk Factors	
High Blood Pressure	20%	Alcohol	57%
Psychiatric Care	13%	Tobacco Use	33%
Diabetes	12%	Recreational Drugs	9%
Lung Disease	12%		

The Applicant provides sufficient support for the proposition that there is patient panel need to integrate dental education with chronic disease management. The student training in the Clinic includes a chronic disease component in the delivery of dental care. The Applicant asserts that the proposed project aims to augment student education and coordination of care around chronic disease.

Impact of Interdisciplinary Care on Total Medical Expenses

Compliance with preventative oral health treatments reduces total medical expenditures for those with chronic illness, regardless of compliance with medical treatment for underlying chronic illness.⁷ Postponing or delaying dental care is correlated with higher disease burden and leads to increased utilization of emergency departments, which often treat the immediate needs of a patient, such as pain, yet rarely address the underlying, and in some cases, more intensive dental care needs.^{8 9}

⁵ *Organized, Evidence-Based care: Oral Health Integration* (Rep.). (2016). Retrieved September, 2017, from Safety Net Medical Home Initiative website: <http://www.safetynetmedicalhome.org/sites/default/files/Guide-Oral-Health-Integration.pdf>

⁶ Petersen, P. E. (2003). *The World Oral Health Report 2003: Continuous improvement of oral health in the 21st century* (Rep.). Retrieved September, 2017, from The World Health Organization website: http://www.who.int/oral_health/media/en/orh_report03_en.pdf

⁷ *Medical Dental Integration Study* (Rep.). (2013, March). Retrieved September, 2017, from UnitedHealthcare website: https://www.uhc.com/content/dam/uhcdotcom/en/Private%20Label%20Administrators/100-12683%20Bridge2Health_Study_Dental_Final.pdf

⁸ N. R., & Auerbach, D. (2016, August 1). *Oral health care access and emergency department utilization for avoidable oral health conditions in Massachusetts* (Issue brief). Retrieved September, 2017, from Health Policy Commission website: <http://www.mass.gov/anf/budget-taxes-and-procurement/oversight-agencies/health-policy-commission/publications/oral-health-policy-brief.pdf>

⁹ Sinclair, S. (2005, February 23). *Cost Effectiveness of Preventive Dental Services*. Washington, DC: Children's Dental Health Project (Issue brief). Retrieved September, 2017, from Children's Dental Health Project website: https://www.cdc.gov/OralHealth/publications/resources/burdenbook/pdfs/CDHP_policy_brief.pdf

Substance Misuse Prevention

Alcohol and tobacco use negatively impact oral health, and substance misuse can decrease access to regular dental care and the practice of preventive oral health measures. The Applicant partnered with the Baker-Polito Administration, the Massachusetts Dental Society, the Harvard School of Dental Medicine and the Tufts University School of Dental Medicine to enhance its curriculum around dental core competencies for the prevention and management of prescription drug use. The partnership is based on recommendations from the Governor's Medical Education Working Group on Prescription Drug Misuse.¹⁰ As such, the Applicant collaborates with the Boston University School of Medicine to train dental students in safe prescribing practices for pain, as well as the appropriate reporting of suspected substance misuse.

Quality Improvement in Public Health

The Surgeon General called for health providers to participate in oral health and the Institute of Medicine (IOM) recommends interdisciplinary collaboration in health care.^{11 12} The Clinic intends to institute an interdisciplinary, collaborative approach to patient care to help address the interdependencies between the management of oral health and chronic conditions. Integrated care has been adopted by dental schools nationally, reflects patient-centered care, and supports the Clinic's focus on population health. The Applicant asserts that this enhanced ability to identify, respond to, and coordinate care for chronic conditions may prevent the onset of chronic disease and may contribute to the prompt diagnosis and treatment of chronic diseases by other healthcare providers.

In 2012, the GSDM implemented the Group Practice Model of Care into the Clinic based on recommendations from the Commission on Dental Accreditation (CODA). The Applicant asserts that the current size of the Clinic and layout of the floors limit both student education and patient care, making implementation of the Group Practice and Integrated Care Team models difficult.

Facility changes incorporated in the proposed project designed to enhance education and patient care include: the renovation of 19,767 GSF and new construction of 13,717 GSF for a total of 33,484 GSF. The size of the operatory (exam rooms) will allow for up to four providers

¹⁰ United States, Massachusetts Department of Public Health. (2016, February). *Governor's Dental Education Working Group on Prescription Drug Misuse*. Retrieved Sept. & Oct., 2017, from : <http://www.mass.gov/eohhs/docs/dph/stop-addiction/governors-dental-education-working-group-on-prescription-drug-misuse-core-competencies.pdf>

¹¹ Crossing the Quality Chasm: A New Health System for the 21st Century. (2001, March). Retrieved September, 2017, from <http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf>

¹² *Oral Health in America: A Report of the Surgeon General* (Rep.). (2000). Retrieved September, 2017, from U.S. Department of Health and Human Services website: <https://www.nidcr.nih.gov/DataStatistics/SurgeonGeneral/Documents/hck1ocv.@www.surgeon.fullrpt.pdf>

in the room at the same time. The project will create dedicated areas to allow for the coordination and continuity of care provided by integrated care teams. Teleconference equipment will allow for the inclusion of healthcare providers outside the dental clinic. The Applicant asserts that these space modifications will allow for the use of integrated care teams and reduce time between cross-professional consultations.

The project will create new entrances to the facility to improve patient flow, enhance patient privacy, and increase comfort for patients. The changes to the facility will improve the Clinic's ability to respond to the patient panel's need for high- quality, low-cost dental care in light of needs to manage chronic conditions and behavioral risk factors connected to their oral health.

The project implementation plan anticipates no interruptions to services or education. The Applicant plans to measure the impact of the project through the evaluation of individual patient dental health records; patient surveys to assess satisfaction with care; and Oral Health Related Quality of Life (OHRQoL) measures. The OHRQoL assessment is GSDM's patient driven evaluation of dental care and health outcomes. The measures captured through a 6-question questionnaire administered at the first appointment establish a baseline. The questionnaire is then administered at each subsequent appointment. Responses to the questionnaires are used to evaluate the impact, from the patient's perspective, of care along the various stages of treatment.^{13 14 15}

Access to Oral Health Services

The Boston University Office of Global and Population Health (the Office) has developed a variety of programmatic responses to further understand and address access to dental and other healthcare services.^{16 17} The Office oversees the Applicant's community programming and supports expanded education and training opportunities for students to support a curriculum that trains students to work with underserved and at-risk populations. Programming provided by GSDM faculty and students includes dental screening, dental health education, and

¹³ Dentists, at the urging of the Surgeon General, and with the support of research, incorporate quality of life measures alongside clinical measures, to provide a more comprehensive assessment of the impact of dental care on a patient's life. Improving a patient's oral health can lead to greater quality of life features, such as eating, socializing, and pain management because of its ability to improve functioning in the areas of a patient's life that may be impaired to due dental disease.

¹⁴ *Oral Health in America: A Report of the Surgeon General* (Rep.). (2000). Retrieved September, 2017, from U.S. Department of Health and Human Services website:

<https://www.nidcr.nih.gov/DataStatistics/SurgeonGeneral/Documents/hck1ocv.@www.surgeon.fullrpt.pdf>

¹⁵ A. S. (2005). Oral health, general health and quality of life. Retrieved Sept. & oct., 2017, from

<http://www.who.int/bulletin/volumes/83/9/editorial30905html/en/>

¹⁶ The Office of Global and Population Health (GPH), reports annually on its programming. The following measures are included in their reporting: types of services provide, number people receiving services, and the various populations served.

¹⁷ *Henry M. Goldman School of Dental Medicine. Global and Population Health. Annual Report 2015-2016* (Rep.). (2016). Retrieved Sept. & Oct., 2017, from Henry M. Goldman School of Dental Medicine website:

<http://www.bu.edu/dental/files/2016/10/GSDM-Community-Programs-Global-Population-Health-Annual-Report-15-16-Final-2-10-06-16.pdf>

referrals to dental and non-dental healthcare providers. GSDM faculty and students provide free dental care in Boston Public Schools and Preschools including preventive services, age-appropriate oral health education, dental screenings, fluoride applications, and sealant placement. Tooth decay, the most common dental as well as chronic disease in children, is associated with lower attendance and academic achievement which reinforces the importance of developing healthy oral habits for children during formative years.^{18 19} Care provided by faculty and students is the primary source of dental care for some students and in many cases their first encounter with a dentist. GSDM student and faculty providers meet patients in the settings where they reside and in so doing address gaps in access to care.

Additional Equipment

As a part of this project, the Applicant proposes to add a second Cone-Beam Computed Tomography (CBCT) unit to improve imaging capabilities in the Clinic and improve patient convenience and access.^{20, 21}

CBCT is a variation of computed tomography (CT) used by dentists to capture 3-dimensional images of dental structures, soft tissues, nerve pathways and bone of the craniofacial region in a single scan using a cone-shaped x-ray beam.^{22 23} CBCT images allow for improved understanding of the extent of dental disease, which ultimately helps the dentist develop more appropriate treatment.²⁴ Traditional dental x-rays provide two-dimensional images, which show the length and breadth of anatomy with distortions, and often require multiple images with multiple doses of radiation exposure to the patient.²⁵ Additionally, 2-D images require

¹⁸ *Organized, Evidence-Based care: Oral Health Integration* (Rep.). (2016). Retrieved September, 2017, from Safety Net Medical Home Initiative website: <http://www.safetynetmedicalhome.org/sites/default/files/Guide-Oral-Health-Integration.pdf>

¹⁹ Petersen, P. E. (2003). *The World Oral Health Report 2003: Continuous improvement of oral health in the 21st century* (Rep.). Retrieved September, 2017, from The World Health Organization website: http://www.who.int/oral_health/media/en/orh_report03_en.pdf

²⁰ CT in general and CBCT specifically are, under the 2017 DoN Required Equipment and Services Guideline subject to review. In this project, the decision to include a second CBCT is analyzed like any other part of the project in the context of how the project addresses the patient panel need, public health value, and operational objectives.

²¹ United States, Massachusetts Department of Public Health, Determination of Need. (2017, January). *Determination of Need Required Equipment and Services Guideline*. Retrieved September, 2017, from <http://www.mass.gov/eohhs/docs/dph/quality/don/guidelines-equipment-and-services.pdf>

²² Dental Cone-beam Computed Tomography. (2017, February 24). Retrieved September, 2017, from <https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm315011.htm>

²³ Imaging Services: Cone Beam Computed Tomography. (2017, January 1). Retrieved September, 2017, from https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Main%20Menu/Tools%20&%20Resources/Policies%20and%20Protocols/Dental%20Clinical%20Policies%20&%20Coverage%20Guidelines/StaticFiles_PDFs/Imaging%20Services_Cone%20Beam.pdf

²⁴ Serota, K. (2017). Cone Beam Computed Tomography: How safe is CBCT for your patients? Retrieved from <http://www.dentaleconomics.com/articles/print/volume-101/issue-1/features/cone-beam-computed-tomography-how-safe-is-cbct-for-your-paitents.html>

²⁵ Id.

multiple rotations of a narrow beam around the patient, delivering more radiation than a single rotation around a patient delivered from a CBCT.²⁶

CBCT is becoming more widely used in dentistry due to its ability to aid in the diagnosis and treatment of oral disease.²⁷ The Applicant currently uses CBCT imaging in the Clinic for dental implants, and as indicated for certain pathologies that appear in an x-ray.

The Applicant asserts that the additional CBCT unit will improve patient flow by having one machine on each treatment floor. The Applicant intends to continue its practice of using CBCT in the limited context of implant placement. Patients are charged a flat rate for the implant irrespective of the number of scans required. The Applicant asserts that its volume of CBCT scans will only increase in the event that its implant practice grows.

In its required reporting to the Department under 105 CMR 100.310(L), the Applicant should comply with recommendations by the FDA and the ADA that clinicians use CBCT only when necessary, “for the diagnosis and treatment of disease” and “when clinical information cannot be provided by other imaging modalities.”^{28 29} In its first report to the Department, the Applicant shall provide the number of scans performed in each of the last three years, the payer mix for reimbursement for the cost of CBCT scans, and the service(s) for which scans were provided. The Applicant commits, as a condition of this DoN, that the volume of the scans provided will not appreciably increase absent evidence of improved efficacy, and that the payer mix will not appreciably change year to year.

Based upon the review of materials submitted by the Applicant, including responses to requests for additional information, and based upon a review of relevant materials regarding the impact of certain policies and practices in oral health, the Applicant has offered clear and convincing documentation that the project is likely to add measurable public health value in terms of improved health outcomes and quality of life for the existing patient panel. The Applicant has addressed the need to provide reasonable assurances of health equity, and will compete in terms of price, total medical expenses, provider costs, and other recognized measures of health care spending.

²⁶ Hurley, M. R. (n.d.). Dimensions In Imaging. Retrieved September, 2017, from <http://www.rdhmag.com/articles/print/volume-33/issue-1/features/dental-hygienists-can-benefit-from-using-cone-beam.html>

²⁷ Dawood, A., Patel, S., & Brown, J. (2009). Cone beam CT in dental practice. *British Dental Journal*, 23-28. Retrieved October, 2017, from <http://www.nature.com/bdj/journal/v207/n1/full/sj.bdj.2009.560.html?foxtrotcallback=true>

²⁸ Dental Cone-beam Computed Tomography. (2017, February 24). Retrieved September, 2017, from <https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm315011.htm>

²⁹ Serota, K. (2017). Cone Beam Computed Tomography: How safe is CBCT for your patients? Retrieved from <http://www.dentaleconomics.com/articles/print/volume-101/issue-1/features/cone-beam-computed-tomography-how-safe-is-cbct-for-your-paitents.html>.

Factor 3

Factor 3 requires compliance with relevant licensure, certification, or other regulatory oversight. The Applicant provided sufficient information in the form of its Affidavit of Compliance and other relevant documentation.

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 impacts or consequences to the existing patient panel.

This project is part of a construction and renovation initiative involving the entire GSDM which includes training laboratories, classrooms, study spaces, lounge and food services. Spaces outside of clinical space dedicated to patient treatment and hands-on clinical training are not subject to evaluation under a DoN.

The DoN regulation at 105 CMR 100.210(A)(4) requires that an Applicant for a DoN provide “sufficient documentation of the availability of sufficient funds for capital and ongoing operating costs necessary to support the Proposed Project without negative impacts or consequences to the Applicant's existing Patient Panel.” Factor 4 continues and requires that the application include an analysis of the Applicant’s finances by an independent Certified Public Accountant (CPA).

The Applicant has received a waiver of the requirement of the CPA analysis, and has instead provided DoN Staff with audited financial statements for Boston University for the year ending June 30, 2016. As noted above, the Applicant is one of the 17 schools of Boston University, and all funding for the Project will come from unrestricted University funds. As such, the primary source of funding will come from University revenue comprised of tuition, fees, and room and board, and not from patient care revenue, which constitutes less than 0.8% of the University’s total revenue.

A review of the audited financials established that the University had unrestricted cash and short-term investments of \$466 million on June 30, 2016, which did not change significantly from the previous year. The capital cost of this project represents approximately 8% of that amount. Staff review of Operating Revenues indicates an excess of revenue over expenses of \$129 million. Further, Moody’s, an independent bond rating agency, improved the University’s credit rating from A2 to A1 in 2017. This change should translate to improved borrowing capacity should the University choose to fund these projects via a bond issue. Staff determined that the Applicant has sufficient funds to support the Proposed Project, and that the Project would not have a negative impact on the Applicant’s Patient Panel. The Applicant asserted that it has no plans to raise the cost of clinical services to cover the cost of the Proposed Project.

Factor 5

Factor 5 requires an assessment of the relative merit of the proposed project compared to alternative methods for meeting the patient panel needs. Staff must find that the Applicant has demonstrated that “the project as proposed is, on balance, superior to alternative and substitute methods for meeting the foreseen health care requirements reviewed under Factor 2, taking into account the quality, efficiency, and capital and operating costs of the project relative to potential alternatives or substitutes, including theoretical as well as existing models” 105 CMR 100.210(A)(5).

The Applicant considered numerous alternatives before selecting the proposed project. These included demolition and rebuilding on the existing site, renovation of an existing alternative building on the Boston University Medical Campus, new construction on one of four alternative BUMC owned parcels, and purchase and renovation of a different property near the BUMC campus.

The GSDM consulted with committees that were aligned with “communities of interest,” such as Education, Clinical, Community and Research, to provide feedback while GSDM developed a plan. The Applicant chose the current plan based on its convenient location on Albany Street, familiarity of patients, students, and faculty with the existing Clinic location, and synergy with existing University and patient communities. When considering alternatives, the Applicant reported that quality of education and clinical care could not be compromised, and that educational and clinical programs would remain open during construction. The current proposed project was chosen because it was the most cost effective choice, and met these other priorities.

Factor 6

In compliance with Factor 6 of the regulations, as a condition of approval, the Applicant will make payment in the amount of \$1,853,834.60 (5% of the total Capital Expenditure of the Proposed Project) to the DoN fund for Community Health Initiative Statewide Initiative pursuant to 105 CMR 100.210(6). This payment will occur within three (3) months after receiving notice and instructions for payment by the Department.

Finding and Recommendation

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 new construction of 13,717 gross square feet (GSF) and renovation of 19,767 GSF of GSDM’s licensed dental clinic, subject to all standard conditions (105 CMR 100.301) and subject to the other conditions set out below, pursuant to 105 CMR 100.360.

Other Conditions

1. GSDM's annual reporting of measures related to the project's achievement of the DoN factors, pursuant to 105 CMR 100.310(L), must specifically include the following:

- a. How implementation of the integrated care model has had an impact on health outcomes and quality of life for the patient panel; and
- b. Documentation that clinician use of CBCT is in line with the FDA and ADA recommendations.

2. In its first report to the Department, the Applicant shall provide the number of CBCT scans provided in each of the last three years, the payer mix for reimbursement for the cost of the scan, and the service(s) for which it was provided. The Applicant commits, as a condition of this DoN, that the volume of the scans provided will not appreciably increase absent evidence of improved efficacy, and that the payer mix will not appreciably change year to year.