



# Department of Health

ANDREW M. CUOMO  
Governor

HOWARD A. ZUCKER, M.D., J.D.  
Commissioner

SALLY DRESLIN, M.S., R.N.  
Executive Deputy Commissioner

February 27, 2019

Dear CEO/CFO/Administrator:

Part 705 of Title 10 of the New York Codes, Rules and Regulations (NYCRR) authorizes the Commissioner of Health to approve time-limited demonstration projects to evaluate the medical efficacy, cost effectiveness and efficiency of, and need for new medical technologies involving innovations in medical equipment or health services, before such equipment and services may be considered as usual, customary and generally accepted modalities of providing patient care.

The New York State Department of Health (Department) convened a special joint meeting of the Health Planning Committee and Establishment and Project Review Committee of the Public Health and Health Planning Council on April 12, 2018 to present the concept and framework for a demonstration program for establishing observation services at cancer care centers located at hospital extension clinics. The materials from that meeting can be located on the Department's website at [https://www.health.ny.gov/facilities/public\\_health\\_and\\_health\\_planning\\_council/meetings/2018-04-12/docs/part\\_705\\_demo\\_project\\_observ\\_beds.pdf](https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2018-04-12/docs/part_705_demo_project_observ_beds.pdf).

The Department is soliciting proposals to implement and evaluate the appropriateness of providing observation services to patients being treated for cancer (infusion and/or radiation) in off-campus hospital extension clinics. Proposed projects to be located in extension clinics that are on a hospital inpatient campus will not be considered for this demonstration project. Applicants must demonstrate the appropriateness for providing observation services in the proposed remote/distant extension clinic location.

## I. Purpose of the Demonstration:

Observation services are post-stabilization services appropriate for short-term treatments, assessment, and re-assessment of those patients for whom diagnosis and a determination concerning inpatient admission, discharge, or transfer can reasonably be expected within forty-eight hours (10 NYCRR 405.32). The delivery of observation services has been recognized and accepted as an effective means of providing necessary care to certain patients. State and Federal regulations require medical oversight, ancillary services and physical environment consistent with inpatient services for patients placed in observation status. Currently, regulations only permit observation services to be provided in the main hospital and division locations.

Hospital extension clinics are not currently recognized as a “usual and customary modality” for providing observation services. With ongoing advances in medical technology and the continued need to innovate to achieve the triple aim of reducing costs, increasing quality and improving patient experience, making observation services available outside of a hospital setting may be a beneficial new model of care. Doing so may enable patients to access appropriate levels of care closer to home, help to alleviate overcrowding at the main clinical

campus of a regional health care system, and leverage telemedicine services in support of observation services. This demonstration program opportunity would allow observation services to be provided in off-campus hospital extension clinics, specifically for patients undergoing treatment for cancer.

Consistent with 10 NYCRR §705.1, the goal of the demonstration project is to determine if the delivery of observation services to cancer patients in off-campus hospital extension clinics is medically effective, can be efficiently provided at a reasonable cost, and supportive of patient need and choice. To that end, the project will evaluate the overall cost effectiveness, quality of care and patient experience.

## **II. Duration of the Demonstration:**

The demonstration project period will be limited to five years. The five-year period will start on the date that health care services become available at the demonstration site. During the demonstration period, approved applicants will be required to submit periodic reports and a final report. An approved project must be operational within six months of the date of the Department's approval of the proposal.

If the Commissioner determines that the project achieved Department goals, applicants participating in the project, and other hospitals, will be able to apply for authorization under provisions in Section 2802 of the Public Health Law and Part 710 of Title 10 of the NYCRR.

## **III. Who May Apply:**

New York State Public Health Law Article 28-licensed general hospitals are eligible to submit proposals for consideration for a demonstration project.

## **IV. Demonstration Project Requirements:**

The following parameters have been established for the Observation Bed Demonstration Project:

- A. A maximum of five projects will be designated statewide. Projects will be reviewed based on the degree to which they are expected to improve access to care.
- B. An individual applicant hospital may submit one proposal and it must be for one extension clinic site.
- C. Observation beds must be located within a licensed hospital extension clinic which is directly controlled by the governing body of the hospital.
- D. No more than three observation beds will be permitted in an approved extension clinic location.
- E. Services are limited to patients over the age of 18 with the primary diagnosis of cancer.
- F. Patients must be undergoing active treatment for cancer (not in remission) and be ambulatory.
- G. The hospital extension clinic providing observation services must operate 24 hours per day, 7 days per week.
- H. Extension clinics providing observation services must be compliant with State and Federal Life Safety Code and Physical Environment regulations applicable to hospital inpatient services. No waivers will be considered for these proposals.
- I. Services provided to patients in observation status must be consistent with all services provided to patients admitted to the hospital. This includes staffing, quality of care, privacy, diagnostic testing, dietary, ancillary, and support services.

- J. Hospital extension clinics providing observation services must ensure the availability of staff and equipment for resuscitation.
- K. Hospital extension clinics providing observation services must establish protocols for transfer and discharge.
- L. Approved extension clinic sites must be operational within six months of the date of the Department's approval of the proposal.

The Department does not anticipate establishing any special Medicaid reimbursement rates, or otherwise providing any extraordinary funding associated with this demonstration program.

#### **V. Data and Reporting Requirements:**

Consistent with 10 NYCRR §705.8, approved applicants must submit reports every six months for the duration of the project. A final report is required within 90 days of the project end date.

Reports must include, at a minimum, the following information, solely related to care provided to cancer patients:

- A. Utilization rates for the extension clinic observation beds and observation beds operated elsewhere in the hospital.
- B. Average charge and cost for the extension clinic observation beds and observation beds operated elsewhere in the hospital.
- C. Patient satisfaction/experience data for the extension clinic observation beds and observation beds operated elsewhere in the hospital. The applicant hospital should include the patient satisfaction/experience measures that are proposed to be used in its application.
- D. Medical and nursing staff experience, including the primary care physician's experience regarding communication and timeliness of information.
- E. Comorbidity analysis of extension clinic versus hospital patients (i.e., what types of patients are being seen at the extension clinic compared to those being seen at the hospital).
- F. Projected impact on case mix at hospital location(s) where the demonstration project patients previously would have been treated.
- G. Telemedicine use by extension clinic physicians and mid-level providers, to capture the volume, type and outcome of telemedicine modalities used. The Department will provide more details prior to the commencement of demonstration adult cancer service delivery at the approved extension clinic site.
- H. Metrics related to timeliness of diagnostic and treatment services received by patients at the extension clinic versus those at hospital location(s). For example, to what degree have patient wait times for visits/services declined? To what degree have wait times in hospital location(s) declined as a result of patients being seen at the extension clinic?
- I. A description of each extension clinic's adult cancer patient population, including but not limited to age categories, length of stay, diagnoses requiring observation stays, treatments provided during observation stays, discharge locations, and reasons for readmission to any setting in subsequent 30 days, if applicable.

In addition, approved programs will be required to report adverse events related to the diagnosis, treatment, and care of adult cancer patients at the extension clinic site. The Department will provide additional information regarding the reporting of adverse events prior to

the commencement of demonstration adult cancer service delivery at the approved extension clinic site.

**VI. Proposal Content:**

Applicants must submit their proposals in the form of a Full Review CON application through NYSE-CON. Applicants should include a written narrative of the proposal not to exceed 30 pages, in the form of a supplemental attachment to the CON application. This narrative should address in detail the framework of the proposal, including, at a minimum:

- A. The name, location, and operating certificate number of the proposed extension clinic site.
- B. The number of observation beds proposed for the site.
- C. The staffing plan for the demonstration project observation services, by shift and discipline.
- D. The annual projected annual utilization and average daily census for the extension clinic observation beds.
- E. The name and location of the hospital(s) at which patients that are expected to utilize services at the extension clinic during the demonstration period, currently receive cancer treatment and related observation services.
- F. The projected impact on annual utilization and average daily census of observation services at those hospital(s).
- G. The projected annual revenue and cost of the proposed project, and the projected fiscal impact on the related hospital(s).
- H. A description of what, if any, telehealth services are projected to be utilized as part of the cancer treatment and observation services provided as part of the demonstration project.
- I. A description of the patient population expected to receive cancer treatment and observation services at the extension clinic, including geographic location, and the anticipated impact on their need for and access to those services.
- J. A description of the medical effectiveness, patient safety, cost efficiency, and patient experience goals of the project, target benchmarks for each goal, and how performance toward achieving each goal will be measured and evaluated.
- K. A description of how the applicant hospital will ensure compliance with State and Federal hospital regulatory requirements for patient services at the extension location. The proposal must specifically describe how the demonstration project will comply with the requirements specified in 10 NYCRR 405.32 Observation services.
- L. A description of how the proposal will address patient safety and patient satisfaction.

**VII. Proposal Review Process:**

Proposals are subject to full review, consistent with 10 NYCRR 705.7. Proposals will initially be reviewed by a Technical Advisory Group (TAG), consistent with 10 NYCRR 705.5. In reviewing applications and making recommendations to the Commissioner, the technical advisory group will consider factors, including but not limited to:

- A. The extent to which an applicant's proposal meets the goals of the demonstration as set by the Commissioner.
- B. The adequacy of the methodology proposed for the demonstration.
- C. The ability of the proposed demonstration to collect data required for an analysis of the project.
- D. The adequacy and appropriateness of the plan for organizing and carrying out the project.
- E. The technical qualifications of the principal investigator and the proposed project staff.

- F. The reasonableness of the proposed budget in relation to the proposed project.
- G. The adequacy of the facility and resources available to the applicant.
- H. Where an application involves activities which could have an adverse health effect upon individuals participating in the demonstration, the adequacy of the proposed means for protecting against or minimizing such effects.
- I. The relevance and status of any approvals required by the Federal Food and Drug Administration or the subject of the demonstration project.
- J. The number of applications to be approved.

Projects recommended by the TAG will be presented to the Public Health and Health Planning Council for its recommendation. The Commissioner will decide the final approval of projects.

#### **VIII. Proposal Submission Process**

**Proposals must be submitted through the New York State Electronic Certificate of Need (NYSE-CON) system, as a Full Review Construction application, no later than 5:00 p.m. Friday, May 31, 2019. The \$3,000 application fee must be received within seven days of application submission, referencing the application submission number, and mailed to:**

Bureau of Project Management  
New York State Department of Health  
Corning Tower, Room 1842  
Albany, NY 12237

Further information concerning this demonstration and the proposal process may be obtained by writing to [CONS@health.ny.gov](mailto:CONS@health.ny.gov). Questions should be submitted by 5:00 p.m. Friday, March 29, 2019. Answers will be posted to the Department's website by 5:00 p.m. Friday, April 12, 2019.

Sincerely,

Daniel B. Sheppard, Deputy Commissioner  
Office of Primary Care and Health Systems Management

New York State Department of Health  
*Observation Beds at Cancer Care Hospital Extension Clinics Demonstration Project*

**Question and Answer**  
**(Questions received between February 27, 2019 and March 30, 2019)**

**Program Specific Questions:**

**Question:** We wish to know if the referenced demonstration requirement is stating that staff (i.e. radiology, laboratory, pharmacy) are required to be on site 24/7 even if some services can be provided without personnel on hand. Any assistance/clarification you can offer is greatly appreciated as we have encountered varied interpretations of this requirement based on how it is worded.

*"I. Services provided to patients in observation status must be consistent with all services provided to patients admitted to the hospital. This includes staffing, quality of care, privacy, diagnostic testing, dietary, ancillary, and support services."*

**Answer:** The applicant must demonstrate how contracting out the required services would provide a comparable level of care to that provided at the main hospital site, specifically, turn-around-time, availability of services 24/7, integration with the medical record, and compliance with applicable requirements for Radiological Services, Laboratory Services, and Pharmaceutical Services in Sections 405.15, 405.16, and 405.17 of 10 NYCRR. In addition, the applicant must include quality metrics that will demonstrate the comparability of these services and provide information on the costs of contracting out services as opposed to maintaining services on-site.