

Proposed Part 705 Demonstration Program for Establishing Observation Beds at Cancer Care Centers Located at Hospital Extension Clinics

Summary and Background:

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 observation services model has been generally recognized and accepted by the health care industry as a means of providing necessary care for patients who are appropriately diagnosed and for whom a determination of facility admission, discharge or transfer can be reasonably expected within 48 hours. Patients may be assigned to observation services only by a physician or appropriately licensed practitioner. With respect to patient care during observation status, State and federal regulations effectively require medical oversight and non-medical services (e.g., dietary, toilet facilities, etc.) that is comparable with hospital inpatient level care. Regulations permit observation services only in a licensed general hospital setting, which has been limited to the main hospital location. Therefore, establishment of observation services in an offsite licensed hospital extension clinic is not currently recognized as a “usual and customary modality” of providing patient care. This demonstration program proposal would allow such services in a hospital extension clinic setting under the limitations described in the “Parameters for Observation Bed Demonstration Program” section below.

In April 2017, Memorial Hospital for Cancer and Allied Diseases (aka Memorial Hospital, Memorial Sloan Kettering, or “MSK”) submitted a Certificate of Need (CON) application to build additional clinic space at Westchester extension clinic in West Harrison. The project (CON #171290) proposed to add six examination rooms and two observation beds. As described in the application, MSK indicated that many of their cancer patients experience symptoms and side effects related to the treatment and/or progression of disease that may require immediate medical evaluation and intervention outside of their physician’s scheduled office hours. MSK further indicated that these patients are frequently evaluated in the Urgent Care Center (UCC) on their Main Campus in Manhattan. Patients treated at the UCC are either discharged to their home, admitted directly to inpatient status at Memorial Hospital, or placed in an observation bed at Memorial Hospital if additional testing and/or evaluation is needed prior to making a decision to discharge or admit for inpatient services. For MSK patients who live in the lower Hudson Valley and Southern Connecticut, the applicant indicated that traveling to Manhattan placed an undue burden on these patients, and that not all patients need the level of services available at the Main Campus UCC. The applicant also indicated that the examination rooms and observation beds at its Westchester extension clinic would

help alleviate overcrowding at the UCC in Manhattan and observation beds at Memorial Hospital.

In its application, MSK indicated that the Westchester extension clinic would be open for unannounced or physician referred visits seven days a week, 24 hours per day. With respect to the observation bed services component of the CON application, MSK proposed 24/7 on-site clinical coverage commensurate with a hospital-based observation unit, as well as 24/7 on-site dietary, laboratory medicine, radiology, and pharmacy.

The Department was generally supportive of the goals of MSK's application (i.e., enabling patients with complex health needs to access appropriate levels of care closer to home; helping to alleviate overcrowding at the main clinical campus of a regional health care system; and leveraging telemedicine services in support of observation services). However, the Department has not permitted establishment of observation services in hospital extension clinic setting, such as MSK's Westchester facility.

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. However, it would not be prudent for the Department to pursue a broad authorization for such a model of care without the opportunity to carefully evaluate the impact on patients, overall cost, overall quality, and on other health care providers in the communities where these hospital extension clinic-based observation services are established. Therefore, it was determined that a statewide Section 705 demonstration project would be an appropriate and effective avenue to evaluate this new model for health services through which regional hospital systems can more effectively manage ambulatory cancer care for their patients.

Part 705 Demonstration Program Approval Process:

The approval of a Part 705 demonstration projects has two distinct phases. The first phase involves the development of the demonstration program and includes the following steps:

1. The Commissioner of Health identifies a medical technology or service to be evaluated through the demonstration project.
2. The Public Health and Health Planning Council (PHHPC) is then afforded the opportunity to review the proposed demonstration program and make recommendations to the Commissioner based on factors including, but not limited to:
 - a. the relative costs associated with acquiring, operating or providing the innovation when compared to the costs associated with other methods of providing comparable services;

- b. the need to demonstrate the medical usefulness of efficacy of the innovation; and
- c. the need to identify and collect data to develop appropriate need and utilization standards for the innovation.

The second phase involves the solicitation, review and approval of project proposals, and follow-up analysis of the projects themselves against the goals of the demonstration program. The second phase includes the following steps:

1. Following consideration of recommendations from PHHPC, the Department develops a Request for Applications to enable review and approval of demonstration projects, and then notifies all medical facilities that provide a level and type of care and service for which the demonstration program is designed of the opportunity to apply.
2. The Commissioner appoints a technical advisory group to review, and make recommendations relating to the selection of applications for demonstration projects.
3. 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; and,
 - j. the number of applications to be approved.
4. Demonstration projects selected by the Commissioner for approval will be subject to full PHHPC review consistent with the requirements for construction application, which affords the Council the opportunity to submit its recommendations prior to a final decision by the Commissioner.

5. Demonstration projects for the proposed Observation Bed Demonstration Program will be limited to five years and, during the course of a project, an approved medical facility shall submit, every six months, written progress reports to the Department in a format prescribed by the Department.
6. Upon completion of an approved demonstration project, the sponsoring medical facility will submit a final written report to the Department in a format prescribed by the Department.
7. The Department/Technical Advisory Group will review and analyze the reports and data submitted by the demonstration projects with respect to the potential overall cost effectiveness (to providers, payers and patients), quality of care, and safety associated with the projects. These finding will be reported to PHHPC in a format and schedule determined by the Commissioner.
8. At the completion of the demonstration program, if the Commissioner determines that the subject service of the program is cost effective and meets generally accepted medical standards for safety and effectiveness, applicants participating in the demonstration, as well as other medical facilities, will be able to apply for authorization to provide the subject service pursuant to section 2802 of the Public Health Law and Part 710 of Title 10 of the NYCRR

Parameters for the Observation Bed Demonstration Program:

The Department will establish parameters for the Observation Bed Demonstration Program for inclusion in the application, which may include, but will not be limited to:

- The number of projects to be designated and geographic distribution. It is recommended that up to five projects will be designated statewide.
- The maximum number of observation beds permitted for a project. It is recommended that no more than three beds be allowed per hospital extension clinic site.
- The observation beds must be located within a licensed hospital extension clinic and directly controlled by the governing body of the sponsoring hospital.
- Only patients over the age of 18 may be admitted to the demonstration project observation services.
- Observation services authorized under this demonstration program must be limited patients with a primary diagnosis of cancer (and that primary diagnosis must be active, not in remission) who are in ambulatory status.

- The hospital extension clinic at which observation services are authorized must operate 7 days per week, 24 hours per day.
- Observation services authorized under this program must be compliant with the life safety code and other physical environment standards applicable to hospital-based observation services.
- The Department does not anticipate establishing any special Medicaid rates or otherwise providing any extraordinary funding associated with this demonstration program.

Observation services authorized under this program must also be compliant with clinical and other operational patient requirements related to staffing, dietary, medication administration, diagnostic testing services, privacy, safety and other federal and New York State operating standards. In addition, the facility must have staff and equipment available capable of rendering resuscitative care and have established agreements and protocols for transferring patients to higher level care. Demonstration program applicants must include a description of the such capabilities and arrangements in their applications.

Data and Reporting Requirements for the Observation Bed Demonstration Program:

The Department will develop and include in the application specific data and other information that demonstration projects must include in the six month and final reports required by Part 705, which may include but will not be limited to:

- Utilization rates for the hospital extension clinic-based observation services beds and estimated impact on utilization of services at the parent institution's main hospital site.
- Discharge information from the hospital extension clinic-based observation services in a manner and form as required by the Department as necessary and appropriate to analyze the goals of the demonstration program and specific project. (e.g., actual length of stay, transfer rate to parent institution's main hospital, transfer rate to other area hospitals).
- Patient clinical and insurance data in a manner and form as required by the Department as necessary and appropriate to analyze the goals of the demonstration program and specific project.
- Hospital inpatient admission or readmission rates for patients utilizing hospital extension clinic-based observation services in a manner and form as required by the Department.
- Cost data in a manner and form as required by the Department as necessary and appropriate to analyze the goals of the demonstration program and specific project.
- Telemedicine use by case type, date/time/outcome/etc.

- Patient experience data for the hospital extension clinic, versus experience at the parent institution's main hospital site; where possible providing patient experience data from patients who have used both sites.
- Physician experience, particularly the primary care physician in relation to care management coordination and transfer of necessary information (e.g., manner in which information is communicated, timeliness of information transfer).
- Comorbidity analysis of hospital extension clinic versus parent institution hospital.
- Projected impact on case mix at parent institution's main hospital site.
- Metrics related to the timeliness of diagnostic services received by observation patients at the extension clinic site compared to the timeliness of those services at the parent institution's main hospital site (e.g., X-ray, CAT scan, MRI).