PHHPC

PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

Empire State Plaza, Corning Tower, Room 1805
Albany, New York 12237

(518) 402-0964
PHHPC@health.ny.gov

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HEALTH PLANNING COMMITTEE

PLACEMENT OF PERCUTANEOUS CORONARY INTERVENTIONS

IN

AMBULATORY SURGICAL CENTERS

INTRODUCTION

In March 2025, the Health Planning Committee of the Public Health and Health Planning Council (PHPPC), in collaboration with the Department of Health, considered **whether and under what terms to authorize cardiac catheterization and percutaneous coronary interventions (PCIs) to be performed in Ambulatory Surgery Centers (ASCs).** "Cardiac catheterization" is a procedure used to diagnose heart disease, whereas "PCI" is a procedure in which stents are placed in blocked coronary arteries.

This topic allowed PHHPC to contribute to health care policymaking in New York and helped prepare members to review future proposed regulations concerning the provision of cardiac catheterization and PCI in ASCs. If new regulations are adopted, PHHPC will then be responsible for reviewing and approving individual applications from ASCs.

The Committee dedicated the past nine months to becoming educated on the topic, obtaining feedback from stakeholders and the public, and preparing recommendations for the Department in three stages:

Stage 1 was dedicated to the Committee educating itself about the performance, complications, and outcomes of PCI in various settings to develop a detailed understanding for this procedure—

one that is often life-saving but can also be life-risking. Meetings included presentations from leaders of the Department's Cardiac Services Program, the Office of Health Services Quality and Analytics, and external experts from the New York State Cardiac Advisory Committee. In addition, data was obtained from various reports, including recently published journal articles reporting early data regarding utilization and safety and through virtual meetings with service directors of other states.

Since the first PCI was performed in New York 1977, the field has seen significant technological innovation and increasing utilization. Over the last two decades, certain hospitals in New York without on-site cardiac surgery have been authorized to perform PCIs. As of 2024, 43 of these hospitals without on-site cardiac surgery, in addition to the 35 hospitals that also provide cardiac surgery, report performing approximately 52,000 PCIs annually. Department data shows that the quality of care and complication rates between these two settings are fully equivalent.

Currently, no freestanding ASCs are allowed to perform PCIs in New York. At the national level, most states allow the performance of PCIs in ASCs with approximately 20 of these states reporting detailed data which indicate that the complication rate in ASCs essentially matches those performed in hospitals at just one percent. One differential to note is that the cost of a PCI in an ASC is approximately 40% lower than one performed in hospitals resulting in a saving of about $4,000. Nevertheless, New York is committed to engaging in detailed, rigorous, and ongoing evaluation before it likewise considers allowing PCI to be performed in ASCs.

In ***Stage II***, the Committee welcomed input and received presentations from key stakeholders including statewide and regional hospital associations, individual hospitals, health care professionals providing cardiac services, and representatives of other health care sectors; and from members of the public and related associations serving to provide the perspective and the experience of patients and consumers. Important concerns were the anticipated loss of revenue by hospitals and hospital systems across the state at this time when many are facing serious financial stress. Conversely, certain hospitals see the movement of low-risk PCIs to ambulatory settings as a benefit due to overcrowding of their inpatient facilities for more complicated cardiac procedures. Additionally, patient advocates stressed the importance of providing clear communication to prospective patients and their families regarding the process of delivering these cardiac services in ambulatory settings along with the need for certain support services in the home. There was also deep appreciation for the prospect of PCIs becoming more available in certain geographic locations, including rural areas.

The Committee also held a meeting with members of the New York State Cardiac Advisory Committee (CAC), who are experts from across the nation appointed by the Commissioner of Health to provide detailed clinical guidance relating to cardiac procedures and care. Since its meeting with the Committee, CAC has formally adopted a series of detailed clinical recommendations if the state does elect to allow PCI in ASCs; these include criteria for patient

selection, staffing qualifications, necessary technology and equipment, available emergency transportation, and follow-up care.

Following much more information gathering than can be contained in this brief overview, the Committee moved to ***Stage III***: deliberation and decision-making to put forward policy recommendations regarding performing PCIs in ASCs. Committee members brought a multitude of experiences and professional perspectives to the table resulting in collegial debate. Nevertheless, members worked closely together with full participation, mutual respect, and remarkable vigor to develop its recommendations. In only one instance, as noted in the recommendations below, was there a divided opinion, resulting in a 6:4 vote.

Ultimately, the Committee developed a recommended process for the Department to begin expanding cardiac catheterizations and PCIs in ASCs. These activities need to be guided by strict regulatory requirements and ongoing evaluation to monitor patient safety and outcomes. Upon close ongoing assessment of the performance of procedures in these settings, the Committee further recommends that the Department consider service expansion in future phases.

The recommendations that follow are the product of this Committee's work described above.

PHHPC Health Planning Committee Recommendations to Full Council

These recommendations are built on the general consensus that was shaped by the Committee's discussions. Where there was a divided opinion, that position is noted in the recommendation.

A. New York should begin a process of expanding diagnostic and interventional cardiac catheterization into ambulatory surgery centers, beginning with low-risk procedures and guided by an evaluation of safety and effectiveness.

B. This process should roll out in phases, with future phases to be guided by the lessons of earlier phases.

C. Specifics of Phase I:

1. A priority of Phase I is to gather important data to evaluate program effectiveness and safety. The Cardiac Advisory Committee will be responsible for identifying appropriate and necessary data collection methods and data elements. Data collection should include a wide variety of indicators including social vulnerability indices and other social determinants of health, including age, payor source, and significant components of access.

2. Phase I should be limited to hospitals with 100% ownership of the ASC.
   NOTE: There was a divided (6:4) position that the hospital need only have ownership control, not necessarily 100%. Subsequent phases may not be limited to hospital ownership.

3. Phase I should be limited to hospitals with existing cardiac surgery programs. The ambulatory surgery centers would be required to use the hospital's quality review and data reporting systems.

4. Phase I should be limited to non-profit ASCs.

5. Phase I Department of Health approvals should be accompanied with a time-limited PHHPC Certificate of Need (CON) approval process and Heath Equity Impact Assessment.

6. Along with clinical patient selection criteria, Phase I needs to include Medicaid and low-income commercial patients as part of the initial rollout.

7. Any site selected under Phase I should have a relevant consumer/patient education program, including patient choice where available.

D. For all Phases of cardiac catheterization, these additional recommendations should be considered:

1. Society for Cardiovascular Angiography and Interventions ethical considerations should be evaluated for incorporation into standards for these ASCs.

2. Require necessary and appropriate staffing and credentialing for ambulatory surgery centers. In addition, require necessary equipment and appropriate safety and emergency protocols consistent with standards.

3. While the authority for monitoring the successive phases of this effort falls to the Department and the Cardiac Advisory Committee, PHHPC should be provided periodic progress reports on the program's evolution, learnings and response to PHHPC's recommendations. Updates should ideally include the financial impact on the health system and individual hospitals as well as identification of possible federal or state payment reforms.

E. If the findings from Phase I show this transition to be both safe and effective, these additional recommendations should be considered:

1. As the phases and learnings evolve, these programs should be located in various geographic and demographic parts of New York State to better understand the impact of using an ambulatory surgical center site.

2. Future site locations could include hospitals with thoracic surgery on site, hospitals without thoracic surgery on site, outpatient procedures at both previously mentioned sites, ambulatory surgical center sites that do not have a hospital on site and free-standing ASCs.