



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

June 2, 2009

Dear Members of the Public Health Council and SHRPC:

I am writing in response to concerns raised by members of both the Public Health Council and the State Hospital Review and Planning Council regarding consideration of applications to establish new ambulatory surgery centers (ASCs). This issue is intertwined with important and challenging questions about the future of hospitals in the face of advances in medical care that are driving services to ambulatory settings, reimbursement for core inpatient services, and the accessibility of services to Medicaid beneficiaries and the uninsured. While this letter does not attempt to address all of these challenges, it does seek to clarify the Department's position on the development of ASCs and sets forth an approach to strengthening the review process for this growing category of providers.

I. Background

As shown in staff presentations to the State Hospital Review and Planning Council (SHRPC) in October, 2008 and to the Public Health Council (PHC) in January, 2009, New York has the second lowest number of ASCs per capita in the country; only Vermont is lower. As further described by staff, studies comparing ambulatory surgery outcomes in hospital outpatient departments, ambulatory surgery centers, and physician offices generally conclude that outcomes are similar, regardless of setting, when risk-adjusted for patient acuity. A high-level comparison of the costs and reimbursement associated with surgery performed in an ASC, hospital, and physician office showed that, on average, procedures tend to be most expensive in hospital settings and least expensive in physician offices, with ambulatory surgery centers in the middle.

The presentations also included a discussion of the factors that should enter into decisions to establish new ambulatory surgery facilities. By statute, the Public Health Council's establishment decisions must be based on public need, character and competence, financial feasibility, and "such other matters as it shall deem pertinent."¹ As discussed at the SHRPC and PHC meetings, the policy considerations that inform the Department's approach to ASC development also include: access to care, cost, quality, consumer preference, and impact on essential services and the health care safety net. The key challenge, as we noted, remains measuring each of these criteria and assigning an appropriate weight to each. The goal is to promote an accessible, high-quality, cost-effective health care delivery system for all patients.

¹ N.Y. Public Health Law §2801-a (3).

II. The Department's Position

The Department views ambulatory surgery centers as an important component of the health care delivery system based upon considerations of access, quality, cost and consumer choice. In addition to offering patients a safe and efficient setting for ambulatory surgery, ASCs, unlike office-based surgery practices, contribute over 9 percent of their revenues to the Health Care Reform Act (HCRA) indigent care pool, but do not receive any distributions from the pool. ASCs can also be an access point for medically-underserved communities, as demonstrated by the Rye Ambulatory Surgery Center's collaboration with the Open Door Family Medical Centers (a federally qualified health center) to provide access to ambulatory surgery services for its Medicaid and uninsured patients.

At the same time, we also recognize the vital role played by hospitals in our health care delivery system, particularly as providers of emergency care, obstetrical services, services to low-income and uninsured individuals and underserved areas, and care for patients with complex medical conditions. Many of these essential services or public goods are not generously reimbursed and are cross-subsidized by services such as ambulatory surgery.

The financial stability of our hospitals and the services they provide to low-income and uninsured individuals are, of course, critical concerns. However, the mere allegation by a hospital that the establishment of a new ASC in its catchment area will have a negative impact on its bottom line should not, without more evidence, be sufficient to block approval of the ASC. In order to influence the review of the ASC application, an objecting hospital should be required to demonstrate with data the projected impact on its revenues and that the projected negative impact will be significant. The impact on the hospital should then be weighed against countervailing considerations, such as consumer preference and expanded access to services.

Some hospital industry representatives have called for a moratorium on ASC development. The Department does not perceive a need for a moratorium. As noted above, New York currently has among the lowest ASC penetrations in the country. And, we have yet to see a wave of approvals of controversial ASCs emanating from the Councils.

III. The Current Review Process

While we do not support a moratorium, we do see room for improvement in the current review process. As described below, our existing regulations and process provide for consideration of access, quality and impact on neighboring hospitals, but they do not indicate how to weigh these criteria.

Our assessment of applications to establish ambulatory surgery centers begins with analyses of public need, financial feasibility and character and competence of the proposed operator. By regulation, the public need criterion includes consideration of the ASC's proposed capacity and its projected utilization, whether the ASC will enhance access to services by underserved groups, and whether the ASC's hours of operation and admission policies will promote the availability of services regardless of ability to pay.

In order to assure that the applicant's projections concerning services to low-income and underserved groups are realized, the Department has, for the past several years, been imposing a limited life of five years on establishments of free-standing ambulatory surgery centers. These facilities are required to submit reports to the Department that include the facility's payor mix, charity care, adverse events, and nosocomial infections. When these facilities near the end of their "limited lives," they will return to the SHRPC and Public Health Council for renewal of their establishment.

In addition to reviews of need, character and competence, and financial feasibility, applications to establish independent ASCs (i.e., those not sponsored by a hospital) are also reviewed for their projected impact on hospitals in the proposed ASC's service area. Developed in 2001 by a joint committee of the SHRPC and the PHC, this element of the review process is based largely on information submitted in response to a questionnaire circulated to nearby hospitals – generally the three hospitals closest to the proposed ASC. The questionnaire is designed to determine the effect of the proposed ASC on the individual hospital's surgical revenues and the impact of any anticipated loss of revenues on the hospital's community-oriented services. It also asks each hospital to describe its charity care activities and to submit audited financial statements from the two preceding fiscal years (see attached copy of a sample letter).

Hospital responses to these questionnaires have come to play a pivotal role in SHRPC and PHC consideration of ASC applications, even when they are vague or unsubstantiated. A number of applications have failed to secure the requisite votes for SHRPC or PHC approval based on minimal or equivocal data. Absent a majority vote for approval or disapproval by the PHC, applications are left in limbo, without recourse to the administrative appeal process afforded by a vote of outright PHC disapproval.

The weight given to hospital objections to ASC's by the SHRPC and PHC is best illustrated by the application of the Long Island Hand and Orthopedic Surgery Center, LLC, of Suffolk County. This ambulatory surgery center application ultimately went before an administrative law judge, who determined the hospital's objections to the application lacked credibility and recommended unequivocally that the Long Island Hand application be approved. Despite the judge's conclusions after hearing evidence from both sides (including the presentation of expert testimony), the application failed to garner sufficient affirmative votes from PHC members to secure its approval. It was not until the judge's recommendation was brought to the Public Health Council for the fourth time that the requisite majority of eight votes for approval were obtained, and the proposed facility could be established.

Some Council members have called for a new ASC need methodology to guide their deliberations. The Department questions whether a new need methodology would lead to more thoughtful decisions on ASC establishment applications or eliminate Council stalemates. I believe that even in the face of demonstrated need based on a numerical need methodology, hospitals will raise concerns about the impact of new ASCs on their revenues, and some Council members will feel compelled to heed those alarms. The real issue is not our method for

determining need, but rather our method for measuring and considering the impact of new ASCs on nearby hospitals.

IV. Strengthening our Approach to ASC CON Reviews

I am mindful of the effects on hospitals of the migration of services from inpatient to outpatient settings. Accordingly, the Department seeks to develop a policy that encourages ambulatory surgery capacity, while safeguarding the financial viability of hospitals. Our experience to date shows a need to develop more precise criteria for evaluating adverse effects of these new surgical facilities on hospitals in a given service area. And, we need to develop a consensus around the appropriate weight to attribute to the impact on hospitals versus other considerations, such as access, cost and consumer preference. While new ASCs in some communities may result in a crippling loss of surgical revenue by a hospital, in other communities a new ASC may simply amount to a healthy source of competition and a new access point for needed services.

The Department will work with hospitals and ASCs and their industry associations to develop more clearly defined guidelines to measure the potential impact on hospitals of proposed ambulatory surgery centers and to assist in weighing that impact against the projected benefits of proposed ASCs.

We look forward to working with you in this important endeavor.

Sincerely,

Richard F. Daines, M.D.
Commissioner of Health



STATE OF NEW YORK
DEPARTMENT OF HEALTH

Hedley Building 433 River Street Troy, NY 12180

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

(Date)

Hospital 1
Hospital Street
Hospital City, New York 10000

Re: CON 000000 _____ Ambulatory Surgery Center

Dear Administrator:

The Department has received a Certificate of Need (CON) application for the establishment of a freestanding ambulatory surgery center (ASC) in _____, which is within the area served by your facility. The applicant and proposed operator is _____ Ambulatory Surgery Center. The proposed location is _____.

The applicant proposes to offer general surgery and to perform 0,000 procedures per year, phased in over the facility's first three years of operation. Enclosed is an excerpt from the application that lists the surgeons who will be operating at the facility.

We invite you to comment on any adverse effects you foresee for your facility if the proposed project is approved. If you wish to respond, please provide information on the following:

- The impact of the proposed ambulatory surgery center on your hospital's community-oriented services. Please be as precise as possible. For example, if you project a loss of revenues to the proposed ASC, please show how this estimate is derived; and please furnish the current costs of the services that would be adversely affected by the establishment of the proposed facility.
- Total utilization of operating room (OR) capacity at your hospital (by percentage) during regular hours and off-hours.
- A breakdown of OR utilization by total inpatient and total ambulatory cases.
- Names of the surgeons on the enclosed list who currently perform surgery at your hospital and the number of ambulatory surgery cases for each in the most recent calendar year for which information is available.

- Whether your facility reserves OR time on a regular basis ("block time") for any of the surgeons in question. If so, please enclose an OR schedule (weekly or monthly) delineating the number of ORs and the times reserved for these practitioners.
- Audited financial statement for the last two years available.
- Expenditures for Bad Debt and Charity Care in your two most recent fiscal years.

Please feel free to enclose any additional information you deem pertinent.

We ask that you share your response to this letter with the applicant at the following address:

_____ Ambulatory Surgery Center
c/o Ms. First Last

_____, New York 01000

Enclosed is a list of other hospitals receiving this letter.

To ensure that the Public Health Council and the State Hospital Review and Planning Council have ample time to consider your comments, please forward your response to the New York State Department of Health, Bureau of Project Management, 433 River Street, 6th Floor, Troy, New York 12180 no later than _____, 200_.

In the meantime you have any questions, please call me at (518) 402-0966 or write via e-mail to cpd02@health.state.ny.us.

Sincerely,

Christopher Delker
Health Program Administrator IV
Division of Health Facility Planning