To Whom it May Concern,

I was recently emailed a copy of the stakeholder letter concerning CON redesign. There is one issue in particular that I think needs to be considered, it is not a problem now, but may become a serious one as payment models change. Currently, medical groups are reimbursed for cases with a professional fee and a facility fee if the facility is licensed. Payment models are changing and in the future there will likely be global payments made to the group to cover both the professional and facility fee.

My concern is that as this happens there will be pricing pressure to have cases done at the lowest cost facility regardless of safety. We know that every licensed ASC is inspected and has oversight. An office based facility has much less oversight and no inspections by the DOH. Is there anything to stop a "mega" group from contracting with an insurance for a global fee and then bringing a kidney transplant or knee replacement or other high complexity case to an office based facility. I do not believe that regulations currently prevent this. Perhaps in the CON redesign, the regulations should spell out the cases requiring a licensed facility or require office based facilities to meet the same high standards as ASC's and hospitals. Otherwise, I fear that pricing pressures will drive cases to offices not equipped to handle the complexity of these cases.

Sincerely

Samuel Beran, MD
Chief, Division of Plastic Surgery, White Plains Hospital

Society of New York Office Based Surgery Facilities
Gastroenterology Pain Management Radiology Dermatology ENT Plastic Surgery and Subspecialties
Advocating for office based surgery facilities in New York State
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March 12, 2013

Karen Lipson
Director
Division of Policy
Office of Health Systems Management

Joan Clancy Miron, MPH
Director
Division of Primary Care Development
Office of Primary Care

NYS Department of Health
Empire State Plaza – Corning Tower
Albany, NY 1227

Dear Ms. Lipson and Ms. Miron,

As the President of the Society of NY Office Based Surgery Facilities (NYOBS), I write on behalf of the interests of nearly 1,000 accredited physician owned ambulatory surgery facilities (aka "OBS") providing critical services to patients across the state. On behalf of our membership, we advocate for increased patient access to safe, quality and cost-effective ambulatory surgical services - *"optimum care, at a better price"*.

We appreciate the opportunity to respond to your letter dated February 25, 2013 soliciting input on recommendations to "update the criteria that trigger the facility licensure requirement and equalize the treatment of physician practices and facilities with respect to Certificate of Need (CON)". More specifically, please allow us to address Questions #4 and #7 regarding the impact of Office-based surgery practice.

A Patient Safety Record Second to None
Studies have shown that with proper quality controls and recent technological advancements, outpatient surgery performed in accredited OBS facilities is as safe, if not safer than any other surgical setting, including hospitals and licensed Article 28 ambulatory surgical centers (ASCs). In addition, New York State's current accreditation law (Public Health Law section 230-d) has made it possible to ensure that surgery performed in OBS facilities meets the highest standards for patient safety. The American Association for Accreditation of Ambulatory Surgery Facilities has compiled safety data (Attachment A) on OBS facilities for many years. Their data on patient outcomes in these facilities represents over 7 million patients and demonstrates an enviable safety record for any industry!

Containing Costs by Preserving our Lowest Cost Provider
Considering the high cost of health care in New York State, we should be focusing our attention on attempting to reduce costs by redirecting the healthcare model to a less expensive method of delivery. Specifically, NYOBS recommends that New York's current policies should be built upon to save the system hundreds of millions of dollars by shifting surgery away from higher cost hospital and ASC settings to the accredited physician owned ambulatory surgery setting where virtually all outpatient surgery can be safely performed at substantially lower costs.

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New York industry-wide survey data (Attachment B) estimates OBS facilities can achieve cost savings of 30% - 40% or more across the most common surgical procedures as compared with licensed Article 28 ASCs and hospitals. Additionally, a recent, large NYC healthcare plan membership study related to colonoscopies demonstrates that the system could conservatively save over $32 million annually on this one, high volume (and mandated) procedure alone! (*See related article* Attachment C).

Additional industry survey data shows that cost-savings are similarly achievable within the state's own Medicaid program. Specifically, a recent survey of our NY membership indicated that 80% of our member facilities would accept Medicaid patients if the facility fee was reimbursed. Currently in New York, accredited OBS facilities are not reimbursed by Medicaid, so those cases must be performed in the more expensive venue of a hospital or an ASC. The amount spent per Medicaid recipient in New York is twice the national average. New York could save hundreds of millions of dollars if our state's Medicaid policies were modernized to recognize accredited physician owned ambulatory surgery facilities for reimbursement.

Accreditation: *The Gold Standard for Patient Safety*

New York has already decided, like most of the rest of the country, that OBS facilities are an important component within the healthcare delivery system. Expanding the CON process to apply to our surgery facilities, however, would dramatically and unnecessarily increase the cost of delivery of healthcare as a result of the increased costs of obtaining a CON. Accreditation, like CON, is also a rigorous and costly process, but unlike CON it is considered the gold standard for patient safety. It is worth noting that in order to maintain accreditation the following minimum standards are required:

- All surgeons must be board certified in their specialty;
- All physicians ACLS/BLS certified and all nursing personnel BLS certified;
- All surgeons must have core privileges to perform all procedures in a near-by hospital;
- Peer Review and Outcomes Reporting are mandatory;
- Compliance with all state, local, federal regulations for: Sanitation, Fire Safety, Building codes, OSHA blood borne pathogens, Americans with Disabilities Act, and HIPPA;
- Advanced instruments and monitoring devices for patient safety during surgery and the post-operative period; and
- Recertification every 3 years with onsite visit by trained/certified physician or physician/nurse inspectors.

Physicians who endeavor to open their own surgery site must expend considerable resources, both in terms of upfront start-up costs as well as on-going monthly expenses. For example, the cost of obtaining accreditation and complying with the on-going recertification process is significant. Although our sites are typically designed to accommodate only one or two surgeons working in a single surgical suite, total development costs can average over two million dollars and monthly operating expenses often run in the tens of thousands of dollars.

Thus, if the goal is to level the playing field among enhanced physician practices, why not "level down" with respect to undue regulatory burdens by eliminating the CON for ASCs while at the same time focus on "leveling up" for the sake of patient safety by instead requiring accreditation for ACSs? Leveling the playing field in this way among these ambulatory surgical settings will lower overall health care costs, and ensure patient access to affordable, quality surgical care.

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Respecting Patient Choice and Improving Participation Rates in Preventive Care

NYOBS also urges the state not to overlook or disregard patient choice and the direct impact it has on issues such as improving women's health care and overall patient participation in critical preventative and therapeutic services. Today, over 90% of breast cancer and breast reconstruction related surgeries are performed in the hospital at substantially higher costs. However, it is well established that the vast majority of patients do not wish to have to go to the hospital when care can be provided elsewhere. Additionally, we know patients are more likely to have a colonoscopy, for example, in the comfort, convenience and privacy of their own doctor's office than elsewhere. Such patient choice factors are critically important in improving both women's health care needs and achieving high participation rates in critical screenings and overall preventative care.

Growing Reimbursement Issues will Cripple Access to Care

Unfortunately, New York State is facing a real healthcare crisis due to a growing physician shortage, including office-based physicians who represent a critically needed provider base. Alarmingly, this crisis is being made worse by the refusal on the part of insurance companies to reimburse accredited physician owned surgery facilities for their related costs. These expenses are substantial and include costs to cover equipment usage, supplies and overhead. That is why NYOBS has engaged policy makers in support of legislation and policy reforms to encourage and restore payment as well as prohibit payers from engaging in disparate treatment among providers performing the exact same covered services within the same class of ambulatory surgical setting. NYOBS encourages the Department of Health to lend its voice to this debate by supporting these thoughtful reform efforts. Without these reforms, more and more accredited OBS facilities will close resulting in decreased access to care and increased cost to our patients. New York State cannot afford to lose any more physicians or small businesses, nor the thousands of jobs we support - not to mention the millions of tax dollars our private facilities generate for local economies and the state.

In conclusion, NYOBS appreciates the opportunity to provide input on these issues that impact our practice and ability to serve our patients. Instead of creating more onerous regulation and barriers that will only serve to drive more private practitioners out of the state, we respectfully request the state turn its attention to reforms centered on: patient safety, lowering costs to the system – both economic and social, increasing patient access to care, respecting consumer choice, thereby improving greater participation in preventative and therapeutic care and maintaining a robust provider base across the state.

Sincerely,

Darrick E. Antell, MD

Darrick E. Antell, MD
President, the Society of
New York Office Based Surgery Facilities

Assistant Clinical Professor of Surgery
Columbia University

ATTACHMENT

A

1.
Patient safety in dermatology: a review of the literature. [Review] [155 refs]
Cao LY. Taylor JS. Vidimos A.
Dermatology Online Journal. 16(1):3, 2010.
[Journal Article. Review]
UI: 20137745
Authors Full Name
Cao, Lauren Y. Taylor, James S. Vidimos, Allison.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=20137745

2.
Evidence-based patient safety advisory: malignant hyperthermia. [Review] [80 refs]
Gurunluoglu R. Swanson JA. Haeck PC. ASPS Patient Safety Committee.
Plastic & Reconstructive Surgery. 124(4 Suppl):68S-81S, 2009 Oct.
[Journal Article. Review]
UI: 20827241
Authors Full Name
Gurunluoglu, Raffi. Swanson, Jennifer A. Haeck, Phillip C. ASPS Patient Safety Committee.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=20827241

3.
Joint Commission of Accreditation of Healthcare Organization accreditation for the office-based oral and maxillofacial surgeon.
Palmer O. McIver P.
Dental Clinics of North America. 52(3):641-51, xi, 2008 Jul.
[Journal Article]
UI: 18501740
Authors Full Name
Palmer, Orville. McIver, Phillip.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=18501740

4.
The importance of advanced cardiac life support certification in office-based surgery.
Rohrich RJ. Parker TH 3rd. Broughton G 2nd. Garza R. Leblanc D.
Plastic & Reconstructive Surgery. 121(3):93e-101e, 2008 Mar.
[Journal Article]
UI: 18317091
Authors Full Name
Rohrich, Rod J. Parker, Thornwell H 3rd. Broughton, George 2nd. Garza, Robert. Leblanc, Danielle.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=18317091

5.
Office-based laryngeal laser surgery: a review of 443 cases using three wavelengths.
Koufman JA. Rees CJ. Frazier WD. Kilpatrick LA. Wright SC. Halum SL. Postma GN.
Otolaryngology - Head & Neck Surgery. 137(1):146-51, 2007 Jul.
[Journal Article]
UI: 17599582
Authors Full Name
Koufman, Jamie A. Rees, Catherine J. Frazier, William D. Kilpatrick, Lauren A. Wright, S Carter. Halum, Stacey L. Postma, Gregory N.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=17599582

6.
Promoting a culture of patient safety: a review of the Florida moratoria data: what we have learned in 6 years and the need for continued patient education. [Review] [20 refs]
Clayman MA. Clayman SM. Steele MH. Seagle MB.
Annals of Plastic Surgery. 58(3):288-91, 2007 Mar.
[Journal Article. Review]
UI: 17471134
Authors Full Name
Clayman, Mark A. Clayman, Scott M. Steele, Mathew H. Seagle, M Brent.

Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medl&AN=17471134

7.
Evidence-based patient safety advisory: malignant hyperthermia. [Review] [80 refs]
Gurunluoglu R. Swanson JA. Haeck PC. ASPS Patient Safety Committee.
Plastic & Reconstructive Surgery. 124(4 Suppl):68S-81S, 2009 Oct.
[Journal Article. Review]
UI: 20827241
Authors Full Name
Gurunluoglu, Raffi. Swanson, Jennifer A. Haeck, Phillip C. ASPS Patient Safety Committee.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medc&AN=20827241

8.
The importance of advanced cardiac life support certification in office-based surgery.
Rohrich RJ. Parker TH 3rd. Broughton G 2nd. Garza R. Leblanc D.
Plastic & Reconstructive Surgery. 121(3):93e-101e, 2008 Mar.
[Journal Article]
UI: 18317091
Authors Full Name
Rohrich, Rod J. Parker, Thornwell H 3rd. Broughton, George 2nd. Garza, Robert. Leblanc, Danielle.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medc&AN=18317091

9.
Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures.
Bitar G. Mullis W. Jacobs W. Matthews D. Beasley M. Smith K. Watterson P. Getz S. Capizzi P. Eaves F 3rd.
Plastic & Reconstructive Surgery. 111(1):150-6; discussion 157-8, 2003 Jan.
[Case Reports. Journal Article]
UI: 12496575

Authors Full Name
Bitar, George. Mullis, William. Jacobs, William. Matthews, David. Beasley, Michael. Smith, Kevin. Watterson, Paul. Getz, Stanley. Capizzi, Peter. Eaves, Felmont 3rd.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medc&AN=12496575

10.
Patient safety in office-based surgery facilities: II. Patient selection.
Iverson RE. Lynch DJ. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Plastic & Reconstructive Surgery. 110(7):1785-90; discussion 1791-2, 2002 Dec.
[Journal Article]
UI: 12447066
Authors Full Name
Iverson, Ronald E. Lynch, Dennis J. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medc&AN=12447066

11.
Patient safety in office-based surgery facilities: I. Procedures in the office-based surgery setting.
Iverson RE. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Plastic & Reconstructive Surgery. 110(5):1337-42; discussion 1343-6, 2002 Oct.
[Journal Article]
UI: 12360080
Authors Full Name
Iverson, Ronald E. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=medc&AN=12360080

12.
The safety of office-based surgery: review of recent literature from several disciplines.
[Review] [38 refs]
Hancox JG. Venkat AP. Coldiron B. Feldman SR. Williford PM.

Archives of Dermatology. 140(11):1379-82, 2004 Nov.
[Journal Article. Review]
UI: 15545548
Authors Full Name
Hancox, John G. Venkat, Arun P. Coldiron, Brett. Feldman, Steven R. Williford, Phillip M.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=15545548

13.
Why are there differences in the perceived safety of office-based surgery?. [Review] [14 refs]
Hancox JG. Venkat AP. Hill A. Graham GF. Williford PM. Coldiron B. Feldman SR. Balkrishnan R.
Dermatologic Surgery. 30(11):1377-9, 2004 Nov.
[Journal Article. Review]
UI: 15522017
Authors Full Name
Hancox, John G. Venkat, Arun P. Hill, Alicia. Graham, Gloria F. Williford, Phillip M. Coldiron, Brett. Feldman, Steven R. Balkrishnan, Rajesh.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=15522017

14.
Efficacy, safety, and cost of office-based surgery: a multidisciplinary perspective.
Balkrishnan R. Hill A. Feldman SR. Graham GF.
Dermatologic Surgery. 29(1):1-6, 2003 Jan.
[Congresses. Research Support, Non-U.S. Gov't. Research Support, U.S. Gov't, P.H.S.]
UI: 12534504
Authors Full Name
Balkrishnan, Rajesh. Hill, Alicia. Feldman, Steven R. Graham, Gloria F.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=12534504

15.

Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures.
Bitar G. Mullis W. Jacobs W. Matthews D. Beasley M. Smith K. Watterson P. Getz S. Capizzi P. Eaves F 3rd.
Plastic & Reconstructive Surgery. 111(1):150-6; discussion 157-8, 2003 Jan.
[Case Reports. Journal Article]
UI: 12496575
Authors Full Name
Bitar, George. Mullis, William. Jacobs, William. Matthews, David. Beasley, Michael. Smith, Kevin. Watterson, Paul. Getz, Stanley. Capizzi, Peter. Eaves, Felmont 3rd.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=12496575

16.
Patient safety in office-based surgery facilities: II. Patient selection.
Iverson RE. Lynch DJ. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Plastic & Reconstructive Surgery. 110(7):1785-90; discussion 1791-2, 2002 Dec.
[Journal Article]
UI: 12447066
Authors Full Name
Iverson, Ronald E. Lynch, Dennis J. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=12447066

17.
Patient safety in office-based surgery facilities: I. Procedures in the office-based surgery setting.
Iverson RE. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Plastic & Reconstructive Surgery. 110(5):1337-42; discussion 1343-6, 2002 Oct.
[Journal Article]
UI: 12360080
Authors Full Name
Iverson, Ronald E. ASPS Task Force on Patient Safety in Office-Based Surgery Facilities.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=12360080

18.
Anesthesia for office-based surgery: are we paying too high a price for access and convenience?.
Arens JF.
Mayo Clinic Proceedings. 75(3):225-8, 2000 Mar.
[Editorial. Historical Article]
UI: 10725945
Authors Full Name
Arens, J F.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=10725945

19.
Office-based surgery and anesthesia: where are we now?. [Review] [7 refs]
Lazarov SJ.
World Journal of Urology. 16(6):384-5, 1998.
[Journal Article. Review]
UI: 9870284
Authors Full Name
Lazarov, S J.
Link to the Ovid Full Text or citation:
http://ovidsp.ovid.com/ovidweb.cgi?T=JS&CSC=Y&NEWS=N&PAGE=fulltext&D=med4&AN=9870284

REVIEW

The Safety of Office-Based Surgery

Review of Recent Literature From Several Disciplines

John G. Hancox, MD; Arun P. Venkat, MBA; Brett Coldiron, MD; Steven R. Feldman, MD, PhD; Phillip M. Williford, MD

Objective: To review recent literature pertaining to adverse outcomes and mortality associated with office-based surgery.

Study Selection: Representative articles from the general and plastic surgery, medical, health regulatory, and dermatology literature.

Data Extraction: Information regarding which surgical treatments should be performed, which specialties should perform them, what level of anesthesia is appropriate, and who should administer it was assessed, with particular attention to issues of patient safety.

Conclusions: Office-based surgery is safe and cost-effective. We caution against attempts to prohibit or severely restrict this important aspect of medical care.

Arch Dermatol. 2004;140:1379-1382

THE NUMBER OF OUTPATIENT surgical procedures has expanded tremendously in recent years, from an estimated 400 000 outpatient procedures performed in 1984 to 8.3 million in 2000.[1] In the 1980s, a shift from inpatient surgery to ambulatory surgery centers (ASCs) occurred,[2] while in the 1990s a shift occurred to physician offices.[3] Patient and physician convenience, ease of scheduling, and avoidance of nosocomial infections are benefits of outpatient surgical procedures. Furthermore, outpatient surgical treatments typically cost 60% to 70% less than similar inpatient procedures.[1] Although most reports have found procedures in ASCs to be safe,[2,4] the lay press and the medical literature have questioned patient safety in physician offices.

See also pages 1333 and 1373

Questions about which surgical treatments should be performed, which specialties should perform them, what level of anesthesia is appropriate, and who should administer it are emphasized in the medical literature. The level of regulation required is another contentious topic, as some have suggested that physician offices lack proper supervision.[1,5] With regard to adverse events and mortality, states have differing methods of obtaining data and, in some cases, have incomplete or no data. Such inadequacies make performing objective studies difficult.[6] Most important is the question of patient safety; if office-based surgery (for select procedures) is as safe as inpatient surgery or surgery in an ASC, then the convenience, cost, and ease of scheduling justify the shift from the hospital to physician offices. One could go so far as to say that the current economic times not only justify but also demand a shift to the outpatient arena, particularly in a medical economic time in which the system is drowning under its own weight.

With this in mind, we review recent literature pertaining to adverse outcomes and mortality associated with office-based surgery. We evaluate representative manuscripts from the general and plastic surgery, medical, health regulatory, and dermatology literature and summarize the findings. From this evaluation of pertinent literature, we conclude that office-based surgery is safe and cost-effective, and we caution against attempts to prohibit or severely restrict this important aspect of medical care.

Author Affiliations: Center for Dermatology Research, Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem, NC (Drs Hancox, Feldman, and Williford and Mr Venkat); and The Skin Cancer Center, Cincinnati, Ohio (Dr Coldiron).
Financial Disclosure: None.

GENERAL SURGERY

From a Medicare database, Fleisher et al[7] evaluated 564 267 total surgical treatments, of which 360 780 were performed in hospitals, 175 288 in ASCs, and 28 199 in physician offices. For all outpatient surgery, mortality rates at 7 days were 41 per

100 000 surgical treatments, and admission rates were 2530 per 100 000 procedures. Multivariate analysis identified advanced age (>85 years), male sex, prior inpatient admission within 6 months, invasive surgery, and the outpatient setting as factors associated with increased risk of death. However, rates were dependent on the procedure. Cataract extraction, hysteroscopy, inguinal hernia repair, arteriovenous grafting, knee arthroscopy, transurethral section of the prostate, and umbilical hernia repair were the riskiest in the outpatient setting; hemorrhoid surgery had a much lower incidence of adverse events in an office. Most important, no deaths occurred the day of surgery in the physician office. The authors emphasize the feasibility of doing database studies to evaluate risk objectively.

PLASTIC SURGERY

Morello and colleagues[8] evaluated adverse events and deaths in more than 400 000 procedures in 241 plastic surgery offices accredited by the American Association for Accreditation of Ambulatory Surgery Facilities during 5 years. The adverse event rate was 0.47%, and there were 7 deaths, for a mortality rate of 1 per 57 000 procedures. They concluded that accredited office-based surgery by board-certified plastic surgeons presents the same risk as surgery in an ASC. In 4778 consecutive office-based plastic surgery cases that included intravenous sedation administered by a board-certified nurse anesthetist, Bitar et al[9] found no deaths, ventilatory requirements, deep venous thromboses, or pulmonary emboli. There were only 12 anesthetic complications, and nausea and vomiting were most common. Another retrospective study[10] of 5316 plastic surgery patients found a complication rate of 0.7%, and most complications were hematomas. Hoefflin et al[11] found no deaths and no significant complications among 23 000 consecutive office-based procedures under general anesthesia. In a smaller prospective study among older patients, Hassan and Hodgkinson[12] found a complication rate of 1.5%. The authors emphasize the feasibility of prospective studies to evaluate the safety of outpatient surgery.

ORAL AND MAXILLOFACIAL SURGERY

The field of oral surgery is rooted in office-based surgery; thus, its literature is relevant to our discussion. In a large retrospective study, Perrott et al[13] evaluated 34 391 cases with a complication rate of 1.3%, all of which were minor and self-limited. By anesthesia type, complication rates were 0.4% with local anesthesia, 0.9% with conscious sedation, and 1.5% with general anesthesia. By questionnaire, D'Eramo et al[14] evaluated adverse events associated with outpatient anesthesia in 1.7 million patients in Massachusetts. Two deaths occurred, and major complications were rare. The most common event was syncope (presumably vasovagal responses), present in 1 of 160 cases with local anesthesia. In contrast, for inpatient facial surgical treatments, Smyth[15] found a 6% complication rate for surgical treatments, including primary closures, local flaps, and grafts. The inpatient surgical treatments may have been more complex or may have been in medically complicated patients.

LIPOSUCTION

Liposuction is the most commonly performed outpatient cosmetic surgery,[6] and articles have focused on deaths and adverse events surrounding it. Platt et al[16] reported 3 deaths and emphasized emboli and hypovolemia as important complications, while Barillo et al[17] discussed 2 cases of necrotizing fasciitis. Rao et al[18] published a high-profile article describing 5 deaths associated with tumescent liposuction or liposuction with dilute local anesthesia. The authors conclude that tumescent liposuction can be risky because of lidocaine toxicity or drug-to-drug interactions. Following that report, several letters to the editor reported similar events, including 6 deaths in southern California[19] and 4 cases of cellulitis in France.[20] Inexperienced physicians or poorly regulated offices have been blamed for complications with liposuction, and calls for legislation-regulated office surgery have been made.[1,5]

Two of the 5 cases that Rao et al[18] discussed in detail involved general anesthesia, and the other 2 included conscious sedation and parenteral anesthesia. This runs contrary to "true" tumescent liposuction, defined by other authors as involving only dilute local anesthesia.[21] The type of anesthesia used is purported to be crucial by many authors. For instance, Hanke et al[22] evaluated the safety of tumescent liposuction (only under local anesthesia) in 15 336 patients by way of a questionnaire. They found no deaths, emboli, perforations of viscera, or thrombophlebitis and concluded that tumescent liposuction is safer than liposuction under general anesthesia. To further stress its safety, Klein[23] reported no deaths with tumescent liposuction under local anesthesia, and Coleman et al[24] reported that 99% of liposuction malpractice cases were associated with systemic anesthesia. Housman and colleagues[25] performed a national survey of more than 500 dermatologic surgeons who perform tumescent liposuction in the United States and found the procedure to be safe, with a complication rate lower than that of hospital-based procedures. Of 66 570 liposuction procedures performed by 267 physicians, no deaths occurred, and the rate of serious adverse events was 0.68 per 1000 cases.

FLORIDA

At the center of the controversy is the state of Florida. In light of emerging regulation of office surgical treatments across the nation, and the mandatory adverse event reporting in Florida, Coldiron[26] evaluated 12 months of office surgery complications. Of 31 procedure-related complications, 6 deaths were recorded. One death occurred after an anaphylactic reaction to radiologic contrast media, and the other 5 involved general anesthesia. Adverse events were more often related to liposuction under general anesthesia than any other procedure. Coldiron[27] also reported that in 2000 and 2001 in Florida there were no injuries or deaths associated with liposuction under local anesthesia. Moreover, 98% of all physicians reporting were board certified; anesthesiologists or nurse anesthetists provided all general and deep sedation, and no physicians performed surgical treatments outside of the scope of their training. Coldiron[26] suggests that the

level of anesthesia, not the location of the liposuction, may be the most important factor to consider.

Vila et al[28] retrospectively evaluated 2 years of office and ASC adverse event data from Florida. Of 13 procedure-related deaths, 5 were related to cosmetic surgery. Eighty-five percent occurred with board-certified physicians, 38% occurred in an accredited office, and 15.4% were under the supervision of an anesthesiologist. The adverse event rates were 66 and 5.3 per 100 000 procedures for offices and ASCs, respectively, and the mortality rates were 9.2 and 0.78, respectively, per 100 000 procedures. They demonstrated a 10-fold increase in adverse events in offices vs ASCs, and they claim that 43 injuries and 6 deaths could have been prevented if all surgical treatments in Florida were performed in ASCs. In unpublished data (A.P.V., January 2004), our group reexamined the Florida data and found no significant difference in adverse events and mortality. We believe that the data by Vila et al underestimated the number of office procedures (the denominator), thus inflating the adverse event rate for offices, and included cases that were outside the study criteria and others that were actually performed in ASCs. The lack of standardization of reporting adverse events for ASCs and office procedures is highlighted by both studies.

DERMATOLOGY

The dermatology literature contains several recent articles pertaining to office-based surgery. Balkrishnan et al[29] reported on a 2002 multidisciplinary conference evaluating the safety of office-based surgery. Researchers and practitioners from dermatology, ophthalmology, otolaryngology, plastic surgery, and anesthesiology demonstrated a low incidence of adverse events along with the benefits of continuity of care, increased patient satisfaction, and decreased nosocomial infections. In another article, Balkrishnan and coworkers[6] performed a national survey of office-based cosmetic surgery adverse event reporting. Of the 48 continental states, only 5 were able to provide complete information about 13 cases of office-based complications. Thirteen states had incomplete information or were unable to provide any information, and 30 states reported no adverse events. Adverse event reporting varied tremendously, and the authors concluded that the data were inadequate to define the safety of office-based cosmetic surgery. The authors call for standardization of reporting complications of office-based surgical treatments so that modifiable risk factors can be identified.

MOHS MICROGRAPHIC SURGERY

Mohs micrographic surgery (MMS) is almost always performed in the physician office. Cook and Perone[30] performed a prospective study of the incidence of adverse events occurring with MMS in 1052 consecutive patients at one center. No deaths occurred, and they found an adverse event rate of 1.64%, with none of the complications resulting in hospitalization. Hematoma and graft or flap necrosis were the most common events. In a prospective study, Otley at al[31] reported low rates of adverse events in 653 patients receiving antiplatelet or anticoagulation therapy. Regarding infection, Futoryan and Grande[32] found that 2.3% of 1047 MMS cases experienced infectious complications. This rate is excellent considering that MMS is considered a "clean contaminated" procedure[33] (with occasional breaks in aseptic technique), in which a 5% to 15% infection rate is acceptable.[34] In fact, this low rate of infection is more consistent with "clean" procedures, in which a 1% to 3% infection rate is acceptable.[35]

COMMENT

Is the physician office the "wild, wild, west of health care," as Quattrone[5] suggests? Is the death rate from office-based liposuction higher than the death rate from motor vehicle crashes or homicides, as Lapetina and Armstrong[1] claim? More than 125 news stories have reported on liposuction-related deaths. Such press is often more powerful than the medical literature in the minds of patients. Our brief review from several disciplines seems to counteract the contention that office surgery is risky. Retrospective and prospective studies indicate that office surgery, in the hands of skilled professionals and with proper patient selection, is as safe as surgery at an ASC or a hospital.

Although conflicting reports exist on the safety of office-based surgery compared with ASCs, one fact seems to be agreed on: adverse event reporting should be uniform so that adequate large-scale studies can correctly assess the risk. Until this is done, no definitive conclusions can be drawn, and opinion may be swayed by anecdotes and hyperbole. The level of anesthesia that is appropriate in the physician office remains debatable, although several studies[9-11,13] we evaluated found that even systemic anesthesia (when done appropriately) is safe.

Another fact that seems to be clear is that procedures involving only local anesthesia or with minimal sedation (including true tumescent liposuction, excision or destruction of benign and malignant lesions, and MMS) are safe. Despite this, a concerning scenario would be the regulation of all office-based procedures. Potential regulations under consideration could mandate physicians to obtain hospital credentials and privileges to perform office-based surgery.[36] This could have a tremendous effect on the practice of many physicians, including dermatologists; the consequence could be an enormous increase in the cost of managing common conditions such as cutaneous malignancies. Chen et al[37] suggested the cost of managing nonmelanoma skin cancer (NMSC) to be 10 times higher in the inpatient setting vs the office ($5537 vs $492), and Manternach et al[36] showed that dermatologists managed 82% of Medicare-related NMSC cases from 1998 to 1999. Given that more than 1.3 million cases of NMSC are diagnosed each year,[38] loss of office-based surgery for this disease alone could increase the cost of managing NMSC by tens of millions of dollars. Given that most NMSC is excised with only local anesthesia, regulating procedures to treat NMSC seems unnecessary. The same could be said for other health care specialties; imagine if all dental work requiring anesthesia was performed in an ASC or hospital!

If all offices were required to be accredited, as some have suggested, this too could have significant consequences for health care payers, including patients with high deductibles or medical savings accounts. Once an office is accredited, additional facility reimbursement for different procedures may be obtainable from private payers (including patients) and Medicare. Such a move would add great expense to the already overburdened system, while eliminating the often unappreciated cost savings of office-based procedures.

We believe that office-based surgery should only be performed by properly trained physicians working within their scope of practice. We also acknowledge that, in selected cases, certified anesthetists or anesthesiologists should administer anesthesia and carefully monitor patients. We also advocate the uniform reporting of adverse events and mortality related to office-based surgery, so that the proper analysis can be performed and patient safety can be assured. With the available data, and in absence of the gold standard of randomized prospective trials, we contend that office-based surgery is safe and cost-effective.

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REFERENCES

1. Lapetina EM, Armstrong EM. Preventing errors in the outpatient setting: a tale of three states. *Health Aff (Millwood).* 2002;21:26-39.
2. Warner MA, Shields SE, Chute CG. Major morbidity and mortality within 1 month of ambulatory surgery and anesthesia. *JAMA.* 1993;270:1437-1441.
3. Rohrich RJ, White PF. Safety of outpatient surgery: is mandatory accreditation of outpatient surgery centers enough? *Plast Reconstr Surg.* 2001;107:189-192.
4. Mezei G, Chung F. Return hospital visits and hospital readmissions after ambulatory surgery. *Ann Surg.* 1999;230:721-727.
5. Quattrone MS. Is the physician office the wild, wild west of health care? *J Ambul Care Manag.* 2000;23:64-73.
6. Balkrishnan R, Gill IK, Vallee JA, Feldman SR. No smoking gun: findings from a national survey of office-based cosmetic surgery adverse event reporting. *Dermatol Surg.* 2003;29:1093-1099.
7. Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients. *Arch Surg.* 2004; 139:67-72.
8. Morello DC, Colon GA, Fredericks S, Iverson RE, Singer R. Patient safety in accredited office surgical facilities. *Plast Reconstr Surg.* 1997;99:1496-1499.
9. Bitar G, Mullis W, Jacobs W, et al. Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures. *Plast Reconstr Surg.* 2003;111:150-156.
10. Byrd HS, Barton FE, Orenstein HH, et al. Safety and efficacy in an accredited outpatient plastic surgery facility: a review of 5316 consecutive cases. *Plast Reconstr Surg.* 2003;112:636-641.
11. Hoefflin SM, Bornstein JB, Gordon M. General anesthesia in an office-based plastic surgery facility: a report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications. *Plast Reconstr Surg.* 2001;107:243--257.
12. Hassan Z, Hodgkinson PD. Adverse events in plastic surgery. *Br J Plast Surg.* 2003;56:41-43.
13. Perrott DH, Yuen JP, Andresen RV, Dodson TB. Office-based ambulatory anesthesia: outcomes of clinical practice of oral and maxillofacial surgeons. *J Oral Maxillofac Surg.* 2003;61:983-995.
14. D'Eramo EM, Bookless SJ, Howard JB. Adverse events with outpatient anesthesia in Massachusetts. *J Oral Maxillofac Surg.* 2003;61:793-800.
15. Smyth AG. A prospective study of 134 consecutive patients requiring diagnosis, excision and repair of a facial cutaneous lesion. *Br J Oral Maxillofac Surg.* 1992; 30:157-160.
16. Platt MS, Kohler LJ, Ruiz R, Cohle SD, Ravichandran P. Deaths associated with liposuction: case reports and review of the literature. *J Forensic Sci.* 2002; 47:205-207.
17. Barillo DJ, Cancio LC, Kim SH, Shirani KZ, Goodwin CW. Fatal and near-fatal complications of liposuction. *South Med J.* 1998;91:487-492.
18. Rao RB, Ely SF, Hoffman RS. Deaths related to liposuction. *N Engl J Med.* 1999; 340:1471-1475.
19. Ginsberg MM, Gresham L. Deaths related to liposuction [letter]. *N Engl J Med.* 1999;341:1000.
20. Vermeulen C, Serra M, Roujeau JC. Deaths related to liposuction [letter]. *N Engl J Med.* 1999;341:1000-1001.
21. Coleman WP III, Glogau RG, Klein JA, et al. Guidelines of care for liposuction. *J Am Acad Dermatol.* 2001;45:438-447.
22. Hanke CW, Bernstein G, Bullock S. Safety of tumescent liposuction in 15,336 patients: national survey results. *Dermatol Surg.* 1995;21:459-462.
23. Klein JA. Deaths related to liposuction [letter]. *N Engl J Med.* 1999;341:1001.
24. Coleman WP III, Hanke CW, Lillis P, Bernstein G, Narins R. Does the location of the surgery or the specialty of the physician affect malpractice claims in liposuction? *Dermatol Surg.* 1999;25:343-347.
25. Housman TS, Lawrence N, Mellen BG, et al. The safety of liposuction: results of a national survey. *Dermatol Surg.* 2002;28:971-978.
26. Coldiron B. Patient injuries from surgical procedures performed in medical offices [letter]. *JAMA.* 2001;285:2582.
27. Coldiron B. Office surgical incidents: 19 months of Florida data. *Dermatol Surg.* 2002;28:710-713.
28. Vila H, Soto R, Cantor AB, Mackey D. Comparative outcomes analysis of procedures performed in physician offices and ambulatory surgery centers. *Arch Surg.* 2003;138:991-995.
29. Balkrishnan R, Hill A, Feldman SR, Graham GF. Efficacy, safety, and cost of office-based surgery: a multidisciplinary perspective. *Dermatol Surg.* 2003;29:1-6.
30. Cook JL, Perone JB. A prospective evaluation of the incidence of complications associated with Mohs micrographic surgery. *Arch Dermatol.* 2003;139:143-152.
31. Otley CC, Fewkes JL, Frank W, Olbricht SM. Complications of cutaneous surgery in patients who are taking warfarin, aspirin, or nonsteroidal antiinflammatory drugs. *Arch Dermatol.* 1996;132:161-166.
32. dFutoryan T, Grande D. Postoperative wound infection rates in dermatologic surgery. *Dermatol Surg.* 1995;21:509-514.
33. Whitaker DC, Grande DJ, Johnson SS. Wound infection rates in dermatologic surgery. *J Dermatol Surg Oncol.* 1988;14:525-528.
34. Silver IA. The physiology of wound infection. In: Hunt TK, ed. *Proposal for the Use of Preventive Antibiotics in Surgery in Wound Healing and Wound Infection: Theory and Surgical Practice.* New York, NY: Appleton-Century-Crofts; 1980: 250-253.
35. Dineen P. Prevention and treatment of deep wound infections. In: *The Surgical Wound.* Media, Pa: Lea & Febiger; 1981:146-149.
36. Mantemach T, Housman TS, Williford PW, et al. Surgical treatment of nonmelanoma skin cancer in the Medicare population. *Dermatol Surg.* 2003;29:1167-1169.
37. Chen JG, Fleischer AB Jr, Smith ED, et al. Cost of nonmelanoma skin cancer treatment in the United States. *Dermatol Surg.* 2001;27:1035-1038.
38. Housman TS, Williford PW, Feldman SR, et al. Nonmelanoma skin cancer: an episode of care management approach. *Dermatol Surg.* 2003;29:700-711.

Mortality in Outpatient Surgery

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Background: The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) has reported statistics on morbidity and mortality for facilities that it accredits based on an analysis of unanticipated sequelae and surgical mortality. Data acquired through the first Internet-Based Quality Assurance and Peer Review reporting system (IBQAP) were reviewed and published in 2004. This article reports the accumulated data in the IBQAP through June of 2006, analyzing death associated with procedures performed in facilities approved by the AAAASF. With the exception of some statistics on the Medicare-aged population, there are few data reported in the literature related to deaths in outpatient surgery.

Methods: The IBQAP, designed in 1999 by the AAAASF, mandates biannual reporting of all unanticipated sequelae and random case reviews by all surgeons operating in AAAASF–accredited facilities. Surgical log numbers, whose entry is required, allow for tabulation of the number of cases and procedures performed by individual reporting surgeons.

Results: In this review of data collected using the IBQAP from January of 2001 through June of 2006, there were 23 deaths in 1,141,418 outpatient procedures performed. Pulmonary embolism caused 13 of the 23 deaths. Only one death occurred as the result of an intraoperative adverse event.

Conclusions: A pulmonary embolism may occur after any operative procedure, whether it is performed in a hospital, an ambulatory surgery center, or a physician's office-based surgery facility. The procedure most commonly associated with death from pulmonary embolism in an office-based surgery facility is abdominoplasty. The frequency of pulmonary embolism associated with abdominoplasty warrants further study to determine predisposing factors, understand its cause, and introduce guidelines to prevent its occurrence. (*Plast. Reconstr. Surg.* 122: 245, 2008.)

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) has reported statistics on morbidity and mortality for facilities that it accredits based on an analysis of unanticipated sequelae and surgical mortality.[1,2] Data acquired through the first Internet-Based Quality Assurance and Peer Review reporting system (IBQAP) were reviewed and published in 2004. A total of 1378 significant unanticipated sequelae and 8 postoperative deaths were documented in 411,617 procedures performed over a 2-year period from 2001 through 2002.[1] The total number of procedures was determined by multiplying the number of cases by 1.4, the average number of procedures per case.

In this review of data collected using the IBQAP from January of 2001 through June of 2006, there were 23 deaths in 1,141,418 outpatient procedures performed. Pulmonary embolism caused 13 of the 23 deaths. Only one death occurred as the result of an intraoperative adverse event. A pulmonary embolism may occur following any operative procedure, whether the procedure is performed in a hospital, an ambulatory surgery center, or a physician's office-based surgery facility.

The procedure most commonly associated with death from pulmonary embolism in an office-

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based surgery facility is abdominoplasty. The frequency of pulmonary embolism associated with abdominoplasty warrants further study to determine predisposing factors, understand its cause, and introduce guidelines to prevent its occurrence.

OVERVIEW OF MORTALITY IN OUTPATIENT SURGERY

Mortality statistics for outpatient surgery are difficult to analyze because of differences in the preexisting general health of patients, the age of patients studied, and the type and number of procedures performed. The majority of outpatient procedures are performed in freestanding or office-based surgery centers in states that do not require accreditation or licensure of outpatient surgery facilities. As a result, there are few reports on surgery outcome data.[3–5]

Before the development by the AAAASF of the IBQAP program in 1999,[1] there was no centrally accessible data acquisition system for outpatient surgery. As a consequence of this lack of centralized reporting, there are few published data relative to postsurgical morbidity and mortality within the first 30 days after surgery from either hospital-based, office-based, or freestanding outpatient surgery facilities.[2,6–12]

In 2004, a study of data obtained from the AAAASF IBQAP program documented eight deaths in 411,617 procedures, or 1.94 deaths per 100,000 procedures.[1] These office-based surgery center procedures, performed in AAAASF–accredited facilities, were captured over a 2-year period from 2001 to 2002.

The current study using the AAAASF reporting system, from January of 2001 through June of 2006, reveals 23 deaths in 1,141,418 procedures, or 2.02 deaths per 100,000 procedures. Thirteen of the 23 deaths (57 percent) were from pulmonary embolism. Only one death occurred as a result of an intraoperative adverse event.

DEATHS

Procedures

The procedure most frequently associated with postoperative mortality is abdominoplasty, followed by face-lift surgery in combination with other related procedures (Fig. 1). Nine of the 12 deaths associated with an abdominoplasty had one or more additional procedures performed at the same time (three patients had one additional procedure, three patients had two). Four of the abdominoplasty patients who died had liposuction as one of the other procedures performed.

CASES

Pulmonary Embolism

Pulmonary embolism accounted for 13 of the 23 deaths (57 percent) reported during the 5½-year period (Fig. 2).

Postoperative Medication Abuse

Three patients died as a result of abuse of postoperative pain medications. The first patient was a 53-year-old Hispanic woman who underwent a mastopexy and removal of breast implants under intravenous sedation. She was seen on the first and fourth postoperative days. There was no indication of postoperative sequelae during those visits. On the fifth postoperative day, she was found dead in her bedroom. There was a history of drug abuse. The suspected cause of death was a pain medication overdose.

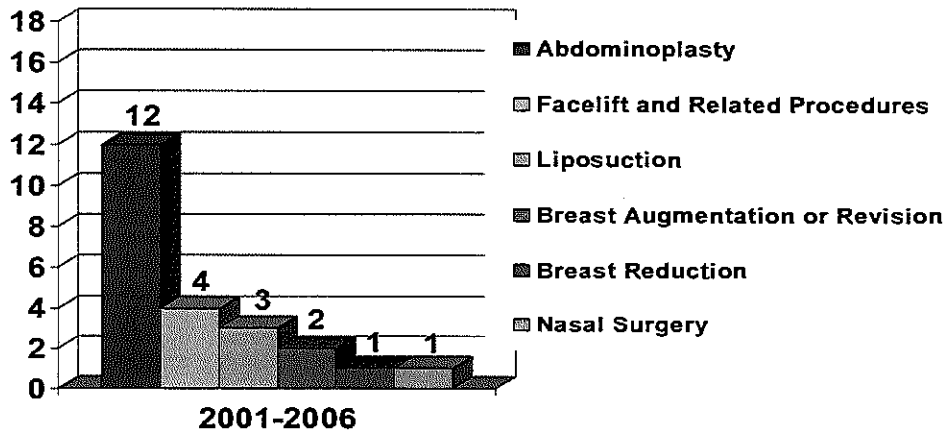

Fig. 1. Bar chart showing the 23 deaths by procedure.

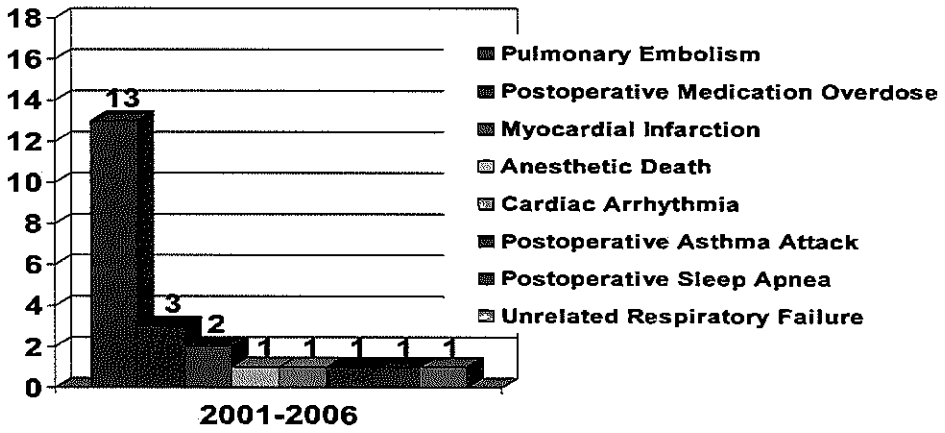

Fig. 2. Bar chart showing the cause of death.

The second patient was a 57-year-old Caucasian woman, who also had a history of drug abuse. She was found dead on the second postoperative day. She had been wearing a fentanyl patch and postoperatively took an unknown quantity of Vicodin orally.

The third patient was a 62-year-old Caucasian woman who died on the second postoperative day after having a face lift with multiple associated procedures. The nurse responsible for her care noted the patient to be somnolent on the evening of her operation. The patient's pain management consisted of the administration of Vicodin and a fentanyl patch. She stopped breathing on the morning of the second postoperative day. She was admitted to the intensive care unit at a nearby hospital, but died as a result of respiratory failure. The suspected cause of her death was a drug overdose leading to respiratory failure.

Myocardial Infarction

A 54-year-old Caucasian woman died 2 days after having an abdominoplasty and liposuction of the back. An autopsy revealed a myocardial infarction.

A second patient, a 45-year-old Caucasian woman, died 3 weeks after abdominoplasty and breast augmentation from ischemic heart disease. There was no known history of cardiac disease before surgery.

Arrhythmia

A 65-year-old Caucasian woman developed an arrhythmia 24 hours after surgery. An autopsy revealed no evidence of myocardial infarction, pulmonary embolism, or medication overdose. There was no history of cardiac arrhythmia before surgery.

Intraoperative Anesthetic Adverse Event

A 67-year-old Caucasian woman underwent a face-lift procedure under intravenous sedation. The operating surgeon, without the assistance of a certified registered nurse anesthetist or anesthesiologist, administered propofol, fentanyl, and midazolam. During the procedure, the patient developed hypotension and bradycardia. She underwent resuscitation and was transferred to a hospital, dying 15 days after admission. On April 14, 2004, the American Association of Nurse Anesthetists and the American Society of Anesthesiologist made the following statement jointly:

> "Whenever Propofol is used for sedation/anesthesia, it should be administered only by persons trained in the administration of general anesthesia, who are not simultaneously involved in these surgical or diagnostic procedures. This restriction is concordant with specific language in the Propofol package insert, and failure to follow these recommendations could put patients at increased risk of significant injury or death."

AAAASF standards now require that the use of propofol be limited to class C facilities accredited for the administration of general anesthesia, or those accredited for the provision of the use of propofol under the direct supervision of an anesthesiologist or certified registered nurse anesthetist.

Asthma

On the evening of her surgery, a 32-year-old Caucasian woman died after a breast augmenta-

tion. She had a history of asthma. While sitting at the dinner table, she became dyspneic with wheezing. She was taken to the emergency room, where she died after unsuccessful resuscitative efforts. An autopsy was not performed.

Sleep Apnea Respiratory Arrest

A 67-year-old Caucasian woman underwent a face-lift procedure. She was reported to have been stable, alert, and oriented in the recovery room 1.5 hours after surgery. She was discharged to her home with a pulse oximeter, which apparently was never placed on the patient. She was found dead the next morning. This case is currently under review.

Respiratory Failure Unrelated to Surgery

A 32-year-old Caucasian woman had a nasal fracture reduced under general anesthesia. Two weeks postoperatively, she developed respiratory distress, presumably caused by chronic obstructive lung disease. She died after having thoracic surgery. The cause of death was lung cancer. The AAAASF standards require all deaths that occur within a 30-day period after surgery to be reported to the central office. This case is included in the study because of that standard.

PULMONARY EMBOLISM

Phases of Surgical Care

Surgical care may be viewed as occurring in three phases: the preoperative phase, during which the patient's overall health is evaluated, an American Society of Anesthesiologists physical status is assigned, and any risk factors for adverse events are delineated; the intraoperative phase, during which the patient's oxygen saturation, end-tidal carbon dioxide, blood pressure, heart rate, and temperature are monitored and documented; and the postoperative phase, during which time the patient's vital signs continue to be monitored until appropriate discharge criteria are met. Documentation of the data produced by these three phases allows for evaluation of quality of care delivered in a variety of settings and provided by physicians trained in different specialties.

Risk Assignment

For this study, all deaths associated with outpatient surgery were analyzed with respect to each of the three surgical phases. Preoperative risk assignment for the patients who died as a result of pulmonary embolism followed the guidelines established by the American Society of Plastic Surgeons Task Force for outpatient surgery for patient safety in office-based surgery facilities.[13,14] The following preoperative factors related to pulmonary embolism were reviewed:

- The use of contraceptives or hormone replacement.
- Family history, with attention to past episodes of thrombosis or embolism.
- Genetic disposition to clotting disorders.
- Edema, swelling, or other signs of venous insufficiency in the lower extremities.
- A history of smoking.

Risk Potential

Risk potential was broken down into high risk, medium risk, and low risk. Of the 13 pulmonary embolism deaths in this report, three patients were taking oral contraceptives or hormone replacement, none were smokers, and no information was available for one. The remaining nine patients had no risk factors for the development of deep vein thromboses or pulmonary embolism.

Risk assignment for the studied pulmonary embolism patients categorized one at low risk, nine at moderate risk, and two at high risk as follows (information about one patient's risk factors could not be obtained):

Low risk: Patients who face uncomplicated surgery and have no risk factors. These patients are usually younger than 40 years of age, although older patients undergoing short procedures may qualify.

Moderate risk: Patients aged 40 years and older who have no additional risk factors but who face procedures longer than 30 minutes. Patients who use oral contraceptives or are on postmenopausal replacement therapy are also at moderate or greater risk.

High risk: Patients older than 40 years with at least one risk factor who face procedures over 30 minutes or longer under general anesthesia and/or have other risk factors.[14]

THE FOLLOWING ARE SUGGESTED FOR THE MANAGEMENT OF PATIENTS ACCORDING TO RISK CATEGORY:

Low risk: The patient should be positioned comfortably on the operating table with the knees slightly flexed. Constriction of the extremities and external pressure should be avoided.

Moderate risk: In addition to the recommendations for low-risk patients, intermittent pneumatic compression devices of the calf or ankle and

frequent alteration of the operating room table are recommended. The devices should be in place before the induction of general anesthesia, and their use should be continued until the patient is awake and moving in the recovery unit.

High risk: In addition to all recommendations for low-risk and moderate-risk patients, both a hematology consultation and preoperative/postoperative pharmacologic antithrombotic therapy should be considered.

Evaluation of patient management in this report demonstrated that 12 of the 12 patients who died as a result of pulmonary embolism had intraoperative placement of sequential compressive devices, eight had postoperative thromboembolic disease stockings, and one patient was treated prophylactically with subcutaneous heparin.

Goldhaber and Berkwits[15] investigated risk factors for pulmonary emboli sustained by women. Smoking, obesity, and hypertension were documented in 280 cases of pulmonary embolism in their study. They noted that women (body mass index $\geq$29.0 kg/m^2) were at an increased risk for the development of deep vein thromboses and pulmonary embolism.

In the AAAASF study, none of the patients who died as a result of pulmonary embolism were smokers. The average height of patients with pulmonary embolism was 5 feet 4 inches, with a range of 62 inches to 69 inches. The weight of patients ranged from 133 to 225 lb, with an average weight of 166 lb. Five of the 12 patients (23 percent) had a body mass index of greater than 30 kg/m^2, while the average body mass index was 29.9 kg/m^2. Data were unavailable for one of the 13 patients.

CONCLUSIONS

Safe surgical practice in the outpatient setting has been difficult to evaluate because of variable methods used to collect data. Also, comparative differences in demographics such as sex, age, race, and health-related characteristics such as body mass index further complicate analysis.

Death rates for procedures performed on Medicare-aged patients have been reported to be as high as 23 per 100,000 when reviewing procedures performed in the outpatient setting in hospitals, ambulatory surgery centers, and office-based facilities.[3] In our study, 23 deaths are reported for 1,141,618 operative procedures performed. The average age for those patients who died was 46 years. Thirteen of these deaths resulted from pulmonary embolism. This represents a death rate of 2.02 per 100,000 procedures performed in facilities accredited by the AAAASF, consistent with the previously reported rate of 1.94 per 100,000 procedures.[1] It is important to note that a pulmonary embolism may occur after any surgical procedure and is unrelated to whether the procedure was performed in an outpatient facility or hospital setting.

Twelve of the 13 pulmonary embolism deaths were associated with abdominoplasty alone or in association with one or more other surgical procedures. The American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery have established guidelines for preoperative evaluation and postoperative management of the patient at potential risk for these serious sequelae.

Only one of the remaining 10 deaths was attributable to an anesthetic event. This death occurred in the absence of a person formally trained in the delivery of intravenous analgesia or general anesthesia. The current standards of the AAAASF mandate that when using propofol during anesthesia, a person trained in general anesthesia, not performing the surgery, be responsible for the anesthetic care of the patient.[16] Three of the deaths were related to pain medication overdose in the first few days after surgery. Another three deaths were the result of cardiac events in the postoperative period. One death was unrelated to the surgical event and two others were secondary to respiratory problems.

Accreditation of outpatient surgery centers is a keystone to patient safety. Only 14 states currently mandate accreditation or licensure of facilities performing outpatient surgery in the United States. Ultimately, all states should require accreditation or licensure for the operation of an outpatient facility. Recognizing the importance of accreditation and licensure, the American Society of Plastic Surgeons and the American Society for Aesthetic Plastic Surgery have mandated that their members operate only in an accredited or licensed facility.[17] The AAAASF has been instrumental in developing standards for accreditation, not only for use by their facilities for use as guidelines for other organizations and states in their accrediting or licensing programs.

Of great importance is the standard that requires surgeons to be board certified in the specialty in which they practice in an outpatient surgery facility. In addition, each surgeon must be certified to perform all procedures in a hospital that they perform in an AAAASF–accredited facility. This standard prevents physicians who have not had formal residency training from perform-

ing procedures outside their scope of practice. The AAAASF accredits outpatient facilities used by many surgical subspecialties.[16]

Before the development of the AAAASF IBQAP program, there was no centralized data collection system for the evaluation of surgical outcomes. Ultimately, a system should be established that encompasses all venues of surgical practice, including inpatient or outpatient hospital-based, freestanding, or office-based facilities. A system that provides comprehensive information about the entire surgical experience will allow for the opportunity to refine patient care and safety.

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REFERENCES

1. Keyes, G. R., Singer, R., Iverson, R. E., et al. Analysis of outpatient surgery center safety using an internet-based quality improvement and peer review program. *Plast. Reconstr. Surg.* 113: 1760, 2004.
2. Morello, D. C., Colon, G. A., Fredricks, S., Iverson, R. E., and Singer, R. Patient safety in accredited office surgical facilities. *Plast. Reconstr. Surg.* 96: 1496, 1997.
3. Pasternak, R. L. Risk assessment in ambulatory surgery: Challenges and new trends. *Can. J. Anesth.* 51: R4, 2004.
4. Fleisher, L. A., Pasternak, R. L., and Lyles, A. A novel index of elevated risk for hospital admission or death immediately following outpatient surgery. *Anesthesiology* 96: A38, 2002.
5. Fleisher, L. A., Pasternak, L. R., Herbert, R., and Anderson, G. S. Admission and death after outpatient surgery in the elderly: The importance of the patient, system, and location of care. *Arch. Surg.* 139: 67, 2004.
6. Singer, R. General anesthesia in an office-based surgical facility: A report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications. *Plast. Reconstr. Surg.* 107: 252, 2001.
7. Rohrich, R. J., and White, P. F. Safety of outpatient surgery: Is mandatory accreditation of outpatient surgery centers enough? *Plast. Reconstr. Surg.* 107: 189, 2001.
8. Byrd, H. S., Barton, F. E., Orenstein, H. H., et al. Safety and efficacy in an accredited outpatient plastic surgery facility: A review of 5316 consecutive cases. *Plast. Reconstr. Surg.* 112: 636, 2003.
9. American Society of Anesthesiologists. Office Based Anesthesia and Surgery. Available at: http://www.asahq.org/patientEducation/officebased.htm. Accessed August 20, 2003.
10. Hoefflin, S. M., Bornstein, J. B., and Gordon, M. General anesthesia in an office-based plastic surgery facility: A report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications. *Plast. Reconstr. Surg.* 107: 243, 2001.
11. Natof, H. E. Complications associated with ambulatory surgery. *J.A.M.A.* 244: 11116, 1980.
12. Bitar, G., Mullus, W., Matthews, D., et al. Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures. *Plast. Reconstr. Surg.* 111: 150, 2003.
13. Iverson, R. E., Lynch, D. J., and the ASPS Task Force on Patient Safety in Office-based Surgery Facilities. Patient safety in office-based facilities: II. Patient selection. *Plast. Reconstr. Surg.* 110: 1337, 2002.
14. Iverson, R. E., and the ASPS Task Force on Patient Safety in Office-based Surgery Facilities. Patient safety in office-based surgery facilities: I. Procedures in the office-based surgery setting. *Plast. Reconstr. Surg.* 110: 1785, 2002.
15. Goldhaber, S. Z., and Berkwits, M. Trials that matter: Can patients with venous thromboembolism be treated with fixed-dose subcutaneous unfractionated heparin? *Ann. Intern. Med.* 145: 929, 2006.
16. American Association for Accreditation of Ambulatory Surgical Facilities, Inc. *AAAASF Standards and Checklist for Accreditation of Ambulatory Surgery Facilities.* Gurnee, Ill.: American Association for Accreditation of Ambulatory Surgical Facilities, Inc., 2005.
17. American Society of Plastic Surgeons and American Society for Aesthetic Plastic Surgery. Policy statement on accreditation of office facilities. American Society of Plastic Surgeons Web site. Available at: http://www.plasticsurgery.org/medical_professionals/health_policy/Policy-Statement-on-Accreditation-of-Office-Facilities.cfm. Accessed August 30, 2007.

Mortality in Outpatient Surgery

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Geoffrey Keyes, M.D., and his fellow authors from the American Association for Accreditation of Ambulatory Surgery Facilities should be congratulated for their most recent report from the Internet-Based Quality Assurance and Peer Review reporting system. The American Association for Accreditation of Ambulatory Surgery Facilities activities such as its role in the January of 2007 Patient Safety Summit Conference and its dedication to continually review, analyze, and report on the Internet-Based Quality Assurance and Peer Review findings, serve as a model for all of organized plastic surgery.

Although this report continues to document an excellent safety record in the American Association for Accreditation of Ambulatory Surgery Facilities–accredited office-based surgery facilities, the authors' key point, that abdominoplasty continues to be the procedure most commonly associated with mortality from pulmonary embolism in the office-based surgery setting, is troubling. This is especially worrisome for two reasons. First, abdominoplasty is a fairly common procedure. According to the American Society of Plastic Surgeons Procedural Statistics, 146,000 cosmetic "tummy tucks" were performed in 2006, making it the fifth most common cosmetic procedure performed. Second, the abdominoplasty–pulmonary embolism connection is a phenomenon that plastic surgeons do not fully understand.

Like all of organized plastic surgery, the American Society of Plastic Surgeons and the Plastic Surgery Educational Foundation recognize that data collection is a critical step toward increasing our understanding and ultimately improving patient outcomes. Not only will data be used to direct and validate clinical practice, it has become a necessary component to promote clinically relevant, evidence-based plastic surgery research. The Plastic Surgery Educational Foundation Research Task Force recognized the need for further study on pulmonary embolism associated with abdominoplasty when, in 2007, it ranked patient safety topics such as deep vein thrombosis as one of its priority topics for funding. In addition, the newly redesigned TOPS 2.0 program is an example of the society's dedication and pursuit of high-quality data. Additional data points have been added to TOPS 2.0 to better assess patient risk factors. Fields have been added to capture body mass index and smoking status and to determine whether an abdominoplasty is associated with massive weight loss.

We all recognize that there are numerous plastic surgery data collection initiatives underway, each of which is driven by the individual organization's needs and objectives. Knowing that these plastic surgery databases exist and contain a wealth of information, the American Society of Plastic Surgeons Data Task Force is investigating how the databases might work together to provide further insights into quality improvement and patient safety. The American Association for Accreditation of Ambulatory Surgery Facilities report was an important factor that helped prompt the Data Task Force to include outcomes associated with abdominoplasty among the first topics it will review.

Enrico Fermi once said, "The beginning of knowledge is the discovery of something we do not understand." Indeed, there certainly is much to be learned in plastic surgery, and most urgently in the area of pulmonary embolism associated with abdominoplasty. Thus, the American Association for Accreditation of Ambulatory Surgery Facilities report should serve as a catalyst for all organizations to seek collaborative opportunities to join forces and answer the many pressing clinical questions faced by plastic surgeons. We must collaborate for the sake of the dedicated plastic surgeons that painstakingly enter clinical information into the plastic surgery databases. Finally, we owe it to our patients. If there is likelihood that sharing data from the various databases will ensure that patients receive the best possible treatment, it is our duty and responsibility to collaborate.

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Mortality in Outpatient Surgery

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We are grateful to the authors for bringing this information to us confirming the safety of outpatient surgery in an American Association for Accreditation of Ambulatory Surgery Facilities–certified facility. This report is timely, providing useful information in recognizing high-risk patients and procedures to reduce mortality in outpatient surgery.

In discussing risk, I inform my patients to forget the word "cosmetic" and remember the word "surgery." All surgery carries risks. In this report, the risk of death was one in 49,626, or approximately one in 50,000 in round figures. This of course compares favorably with the risk of dying in an automobile accident at one in 5000 but pales when compared with the risk of flying at one in 11 million.[1]

Three factors influence the level of risk: the patient and procedure, the surgeon, and the facility where the procedure is performed. The patient's medical history and general health, and whether the patient reveals his or her complete medical history and truthfully responds to the surgeon's questions, will also impact risk. The surgical training, skill, and commitment of the surgeon to patient safety are the second factor. The facility is the third component of risk. These three factors fit well the triangle adopted by the American Society for Aesthetic Plastic Surgery as our logo promoting the culture of safety (Fig. 1).

This review sheds light on two sides of the triangle: (1) the patient and procedure and (2) the surgical facility. Although there is risk regardless of where the procedure is performed, the authors clearly demonstrate that the risk in an American Association for Accreditation of Ambulatory Surgery Facilities–approved facility is consistent when the figures from the current study are compared with their previous publication in 2004.[2] Regrettably, as the authors point out, there are no published series on surgical morbidity and mortality from either hospital-based, office-based, or freestanding outpatient surgical facilities for comparison. The only available data quoted by the authors[3] are the death rates of Medicare age patients undergoing surgical procedures performed in outpatient settings in hospitals,

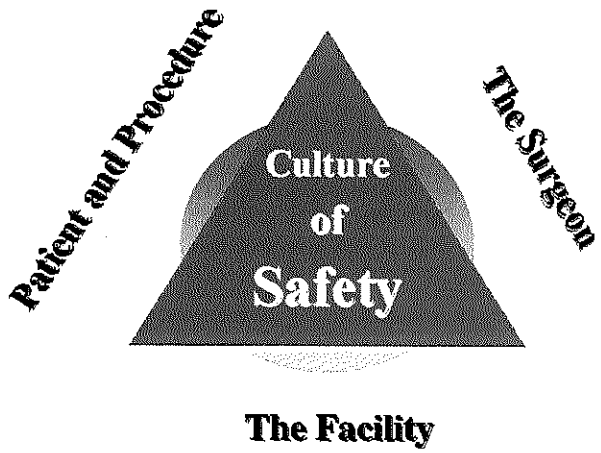

Fig. 1. American Society for Aesthetic Plastic Surgery logo promoting the culture of safety.

ambulatory surgery centers, and office facilities, with a mortality rate 12 times that reported in this series. These data serve to emphasize the role played by the patient's general health and the procedure performed.

Convinced that surgical facilities certified by American Association for Accreditation of Ambulatory Surgery Facilities provide safe environments for outpatient surgical procedures, both the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons several years ago established a policy that all members must perform outpatient surgery in such inspected and certified outpatient surgical facilities to maintain membership in the societies. So compelling is the safety afforded in such centers that the International Society of Aesthetic Plastic Surgery in cooperation with Surgical Facility Resources, a subsidiary of the American Association for Accreditation of Ambulatory Surgery Facilities, has recommended that its members also practice in facilities inspected and certified by Surgical Facility Resources or a similar national entity. There is no question that such facilities are superior to and safer than the alternative, unregulated office

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facilities. The proverbial back room in the doctor's office is not a safe place for outpatient surgical procedures.

An analysis of the 23 deaths in this series not only underscores the importance of patient and procedure as risk factors but also serves to direct our attention toward prevention in the future. There is a clear indication here where, of the 23 deaths, 13 (57 percent) were related to pulmonary embolism. The indication is that this is an area where we have to concentrate our prevention efforts. Venous thromboembolism is not unique to outpatient surgical centers and is a risk factor following surgery regardless of location. However, it is imperative for us as plastic surgeons performing outpatient procedures to recognize this risk and take every possible measure to prevent venous thromboembolism. It comes as no surprise that the procedure most frequently associated with postoperative mortality was abdominoplasty—12 deaths—but I was surprised to see that it was followed by face lift in combination with other procedures, with four deaths.

Abdominoplasty is established as carrying the highest risk in outpatient aesthetic surgery. Recognizing this, we must redouble our efforts to reduce risk with abdominoplasty, in particular, those associated with venous thromboembolism.

There are several excellent publications outlining steps that could be taken to reduce the risk of venous thromboembolism.[4] Universal application of these recommendations will further improve safety of outpatient abdominoplasty.

It is remarkable that only one of the 23 mortalities was anesthesia related. Interestingly, the anesthetic was administered not by an anesthesiologist, anesthesia physician's assistant, or nurse anesthetist but by the operating surgeon. Even though this is a single isolated mortality, it raises the greater issue as to who should be administrating anesthetic agents such as propofol. I believe the message is clear here that general anesthetic agents should only be administered by those trained and qualified to do so. It is not in the best interest of the patient or surgeon for the surgeon to act as surgeon and anesthetist simultaneously. Even though there was only one death in this category, the message is that we should do what we do best, operate, and allow those trained in anesthesia to do what they do best, administer general anesthetics. We must not allow cost to compromise patient safety.

Although totally risk-free aesthetic surgery may be an elusive goal, this extensive report is an indication of where we are with our efforts to improve patient safety and where we should concentrate our efforts from here on. The report reinforces the commitment made by our two major societies, the American Society for Aesthetic Plastic Surgery and the American Society of Plastic Surgeons, to patient safety. It confirms our decision to mandate that our members only operate in accredited facilities.

The information provided here will guide our future efforts. As we continue to promote patient safety, we must look at reducing the risks associated with abdominoplasty, combined procedures, and most of all deep venous thrombosis following outpatient surgery. I was surprised to see that even a breast augmentation, a straightforward 1-hour procedure, had resulted in a deep venous thrombosis.

Although the environment and marketplace in which we practice may be driven by cost and sometimes cost only, we as American Board of Plastic Surgery–certified plastic surgeons, members of the American Society for Aesthetic Plastic Surgery and American Society of Plastic Surgeons, must hold ourselves to higher standards. Although we are all cost conscious, we should not sacrifice patient safety in the interest of lowering costs. We make a commitment yearly when we sign an affidavit on our dues forms for our two societies that we will only operate in accredited facilities. We should also make a similar commitment that we will not cut corners in our operating rooms and practices to save money to reduce fees at the risk of impacting patient safety. We should continue to do what we do best—operate—and provide our patients with excellent preoperative and postoperative care and allow other experts such as anesthesiologists to administer anesthesia. Again, my thanks to the authors for this review, which should be our guide as we move forward with our efforts to improve patient safety and to minimize morbidity and mortality in outpatient surgical procedures.

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REFERENCES

1. Airplane Disasters and Plane Crash Statistics. http://www.fearlessflight.com. Accessed January 31, 2008.
2. Keyes, G. R., Singer, R., Iverson, R. E., et al. Analysis of outpatient surgery center safety using an internet-based quality improvement and peer review program. *Plast. Reconstr. Surg.* 113: 1760, 2004.
3. Reuven, P. L. Risk assessment in ambulatory surgery: Challenges and new trends. *Can. J. Anesth.* 51: R4, 2004.
4. Young, V. L., and Watson, M. E. Continuing medical education article: Patient safety. The need for venous thromboembolism (VTE) prophylaxis in plastic surgery. *Aesthetic Surg. J.* 26: 157, 2006.

Special Topic

Analysis of Outpatient Surgery Center Safety Using an Internet-Based Quality Improvement and Peer Review Program

Geoffrey R. Keyes, M.D., Robert Singer, M.D., Ronald E. Iverson, M.D., Michael McGuire, M.D., James Yates, M.D., Alan Gold, M.D., and Dennis Thompson, M.D.

Assessing the quality of care delivered in office-based outpatient surgery centers is difficult because formerly there was no central data collection system. The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), in its ongoing effort to assess and improve patient care, has developed an Internet-based quality improvement and peer review program to analyze outcomes for surgery centers it accredits. Reporting is mandatory for all surgeons operating in AAAASF-accredited facilities. Each surgeon must report all unanticipated sequelae and at least six random cases reviewed by an accepted peer review group biannually. A total of 411,670 procedures were analyzed during a 2-year period (from 2001 to 2002). There were 2597 sequelae reported during this period. The most common sequela was hematoma formation following breast augmentation. Infection occurred in 388 cases. Deep vein thrombosis, pulmonary embolism, and intraoperative cardiac arrhythmias were found to occur in a frequency consistent with previous reports. Significant complications (hematoma, hypertensive episode, wound infection, sepsis, and hypotension) were infrequent. A total of 1378 significant sequelae were reported for 411,670 procedures. This calculates to one unanticipated sequela in 299 procedures (an incidence of 0.33 percent). Seven deaths were reported. A death occurred in one in 58,810 procedures (0.0017 percent). The overall risk of death was comparable whether the procedure was performed in an AAAASF-accredited office surgery facility or a hospital surgery facility.

This study documents an excellent safety record for surgical procedures performed in accredited office surgery facilities by *board-certified surgeons.* (*Plast. Reconstr. Surg.* 113: 1760, 2004.)

The number of outpatient surgery centers and physician office–based surgery facilities is escalating dramatically.[1,2] This phenomenon is in direct response to the demand for safe, cost-effective surgical care for procedures that can be performed in an outpatient setting. There are advantages to performing operations in an outpatient setting for both patients and surgeons, including convenience, patient privacy and comfort, consistency in nursing and support staff, and increased efficiency.[3]

The American Society of Anesthesiologists predicts that by the year 2005, an estimated 10 million procedures will be performed annually in doctors' offices—twice the number of office-based operations performed in 1995.[4] This dramatic increase in the number of procedures performed in outpatient surgery centers has focused attention on the need for accreditation as a means of ensuring compliance with standards for their safe operation.[5,6]

Currently, only 14 states have mandated accreditation of surgery centers. The number of states requiring accreditation or licensure to perform surgery in an outpatient setting will, and should, continue to increase, until accreditation becomes the national standard.

In the spring of 1999, recognizing the importance of accreditation, the American Society of Plastic Surgeons and The American Society for Aesthetic Plastic Surgery passed a joint mandate for all of their members stipulating that members who perform outpatient operations under sedation or general anesthesia do so in an accredited or state-licensed facility.[7] Accredited or licensed outpatient surgical facilities must meet at least one of the following criteria[7]:

- Be accredited by a nationally recognized or state-recognized accrediting agency or organization, such as the American

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Association for Accreditation of Ambulatory Surgery Facilities (AAAASF), Accreditation Association for Ambulatory Health Care, or the Joint Commission on the Accreditation of Healthcare Organizations.
- Be certified to participate in the Medicare program under Title XVII.
- Be licensed by the state in which the facility is located.

Monitoring Surgery Center Management

Design and management of a surgery center require compliance with nationally recognized standards to safeguard patient care. Ongoing monitoring of care delivery is vital to ensure patient safety. However, it is difficult to compile and compare the data documenting care delivery. This difficulty is a consequence of lack of centralization of data collection from the multiple accrediting, licensing, and managing entities of outpatient surgical facilities. As a result, there is little available coordinated information concerning ultimate outcomes of outpatient surgery in nonhospital settings.

Since 1982, AAAASF, the largest organization in the United States that accredits single or multispecialty office-based surgery centers, has been at the forefront of developing safety standards for the operation of outpatient surgery centers and coordinating relevant data. In 1996, AAAASF conducted a voluntary survey of all of their accredited surgery centers to assess outcomes of surgical care. The directors of all the surgery centers were asked to fill out questionnaires about unanticipated sequelae that occurred in their facilities. Of the 418 facilities accredited at that time, 241 (57.7 percent) returned the anonymous questionnaires, a very high response rate. In 1997, Morello, Colon, Fredricks, Iverson, and Singer published a review of this survey, entitled "Patient Safety in Accredited Office Surgical Facilities."[8]

The following findings were of interest:
- 400,675 operative procedures were reported during a 5-year period from January 1, 1989, to December 31, 1993.
- Significant complications (hematoma, hypertensive episode, wound infection, sepsis, and hypotension) were infrequent, numbering 1877, for an occurrence of one in every 213 cases, or 0.47 percent.
- Return to the operating room within 24 hours and precautionary hospitalization were less frequent.
- Seven deaths were reported. A death occurred in one in 58,810 procedures (0.0017 percent). The overall risk of death was comparable whether the procedure was performed in an AAAASF-accredited office-based surgery facility or a hospital surgery facility.[8,9]

This study documented an excellent safety record for surgical procedures performed in accredited office-based surgery facilities by board-certified surgeons.

Quality Improvement and Peer Review

The goal of a surgery facility is to provide the highest level of care delivery. The facility, whether office-based, free-standing, or in a hospital, should provide care with positive outcomes and a reduced incidence of unanticipated sequelae. In an effort to improve quality of patient care, AAAASF designed and adopted the first Internet-based reporting system for quality improvement and peer review. The purpose of the Internet system was twofold: to improve monitoring of random case review and unanticipated sequelae and to facilitate collation and analysis of the data acquired. This system has provided AAAASF with the ability to more precisely evaluate outcomes.

The guidelines for using this new reporting system follow AAAASF standards,[9] which require facilities to institute an ongoing quality improvement program that (1) monitors and evaluates the quality of patient care, (2) evaluates methods to improve patient care, (3) identifies and corrects deficiencies within the facility, and (4) alerts the medical director to identify and resolve recurring problems.

Peer review must be performed every 6 months and must include reviews of both random cases and unanticipated operative sequelae. If peer review sources external to the facility are used to evaluate delivery of surgical care, the patient consent form is so written as to protect confidentiality of the medical records, consistent with current legal standards. Peer review is performed either by a recognized peer review organization or by a physician other than the operating surgeon.

A minimum of six random cases per surgeon utilizing the facility must be reviewed, and for group practices, 2 percent of all cases performed must be reviewed every 6 months. These random case reviews must include assessment of the following: (1) thoroughness and legibility of the history and physical exam-

ination; (2) adequacy and appropriateness of the surgical consent form; (3) presence of appropriate laboratory, electrocardiographic, and radiographic reports; (4) presence of a dictated operative report or its equivalent; (5) anesthesia record for operations performed with intravenous sedation or general anesthesia; (6) presence of instructions for postoperative and follow-up care; (7) and documentation of unanticipated sequelae.

All unanticipated operative sequelae are reviewed, including, but not limited to the following: (1) unplanned hospital admission; (2) unscheduled return to the operating room for complication of a previous procedure; (3) untoward result of a procedure, such as infection, bleeding, wound dehiscence, or inadvertent injury to another body structure; (4) cardiac or respiratory problems during stay at the facility or within 48 hours of discharge; (5) allergic reaction to medication; (6) incorrect needle or sponge count; (7) patient or family complaint; (8) equipment malfunction leading to injury or potential injury to patient; and (9) death.

Each unanticipated operative sequela chart review includes the following information, in addition to the operative procedure performed: (1) identification of the problem; (2) immediate treatment or disposition of the case; (3) outcome; (4) analysis of reason for problem; and (5) assessment of efficacy of treatment.

The data obtained through the individual surgery center peer review meetings are then entered into the Internet quality improvement and peer review program.

Data obtained from 621 surgery centers from 2001 through 2002 were statistically analyzed. The AAAASF standards require a bound surgical log book be kept that records sequentially all operations performed. The first and last surgical log numbers of all reviewed random cases and unanticipated sequelae from a reporting period are entered into the Internet program with the reported data. This allows for the computation of the total number of cases performed per surgeon per period. In this study, 73 percent of reporting surgeons correctly entered their surgical log numbers. The average number of cases for those surgeons was assigned to the surgeons whose numbers were not correctly entered. The average case consisted of 1.37 procedures. Using this multiple, the total number of procedures reported for this study was 411,670.

A total of 2597 sequelae in 411,670 procedures were reported. The standards for AAAASF require *all* unanticipated sequelae to be reported, including patient complaints, surgery cancellations, and a variety of sequelae deemed less significant than those reported by Morello et al.[8]

When analyzing data in this report comparable to data in the aforementioned article, a total of 1378 significant sequelae were reported in 411,670 procedures over a 2-year period (from 2001 to 2002). This calculates to one unanticipated sequelae in 299 procedures (an incidence of 0.33 percent) compared with one in every 213 cases, or 0.47 percent, for the Morello et al.[8] article.

Recently, Byrd et al.[2] reported 35 unanticipated sequelae in 5316 cases. The 0.7 percent incidence of unanticipated sequelae in their study, conducted over a 6-year period, supports the incidence found in the current study.

Analysis of Sequelae

Table I lists the 1378 reported sequelae by type in descending order of frequency.

Hematoma

Hematoma was the most common unanticipated sequela reported in the study. There were a total of 740 hematomas reported, representing 28 percent of all sequelae or 0.18 percent of all procedures. The majority of hematomas (n = 676) were managed on an outpatient basis (Fig. 1). Sixty-four patients with hematoma required hospitalization

TABLE I
Sequelae*

Sequelae	No.
Hematoma	740
Infection	388
Necrosis	76
Cardiac events	29
Respiratory distress	20
Pneumothorax	19
Burn	19
Pulmonary embolism	17
Deep vein thrombosis	14
Hypotension/hypertension	16
Pulmonary edema	11
Allergic reaction	6
Cellulitis	6
Death	6
Hypoxia	5
Cardiac arrest	2
Chest pain	2
Hyperthermia	2

*Total number of sequelae = 1378.

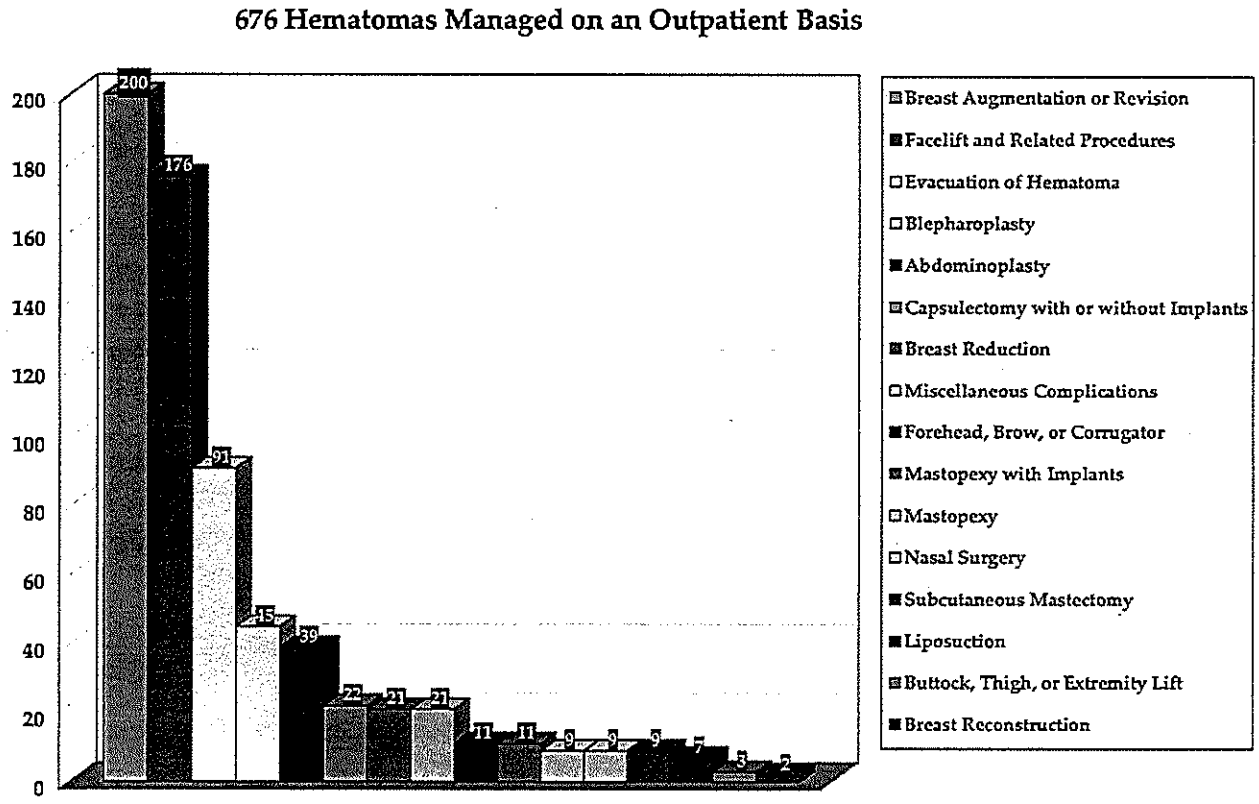

FIG. 1. Hematomas managed on an outpatient basis (n = 676).

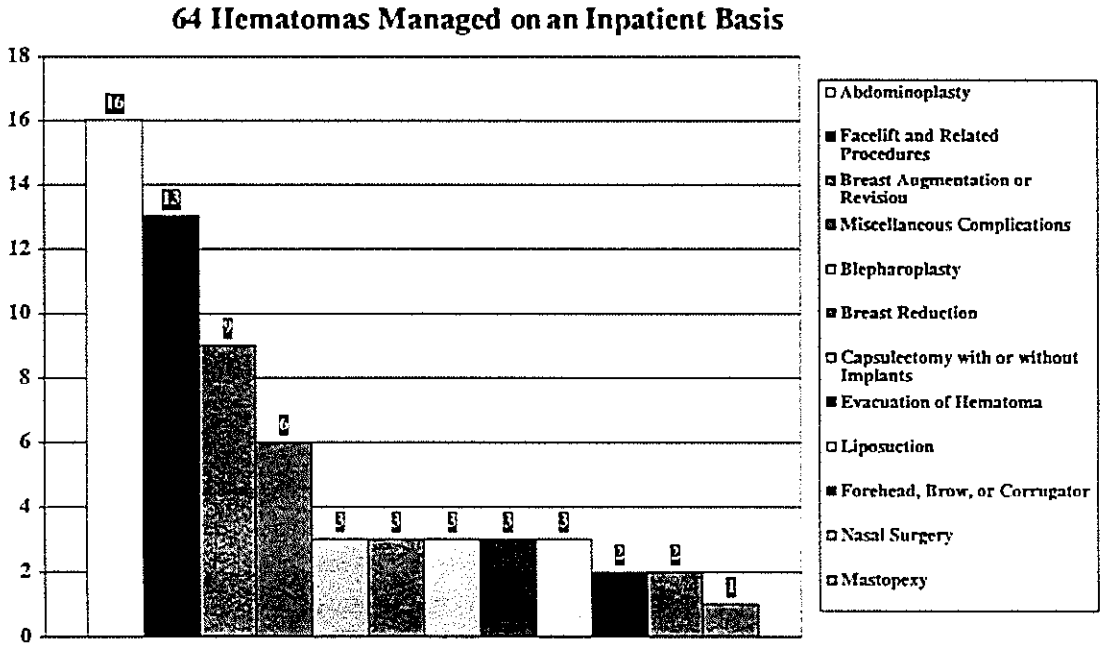

FIG. 2. Hematomas managed on an inpatient basis (n = 64).

(Fig. 2). Of those patients hospitalized, three patients were hospitalized for observation and had no surgical intervention. The average hospital stay for these patients was 1.38 days (range, 1 to 6 days).

Breast augmentation resulted in the largest

number of hematomas managed as outpatient cases (n = 200). Abdominoplasty accounted for the largest number of patients hospitalized with hematomas (n = 16). All hematomas were managed successfully without residual sequelae. No deaths were reported as the result of hematomas.

Morello et al.[8] reported hematoma or bleeding episodes in 965 of the 400,675 operative procedures, or one in every 415 procedures (an incidence of 0.24 percent). Byrd et al.[2] reported that 77 percent of sequelae were hematomas, an incidence of 0.5 percent or one in 200 procedures. Natof[10] performed a prospective study on 13,433 procedures with a follow-up of 14 days. Bleeding occurred in 74 patients, or one in 182 procedures (0.55 percent).

Infection

There were 388 infections reported, representing an incidence of 0.09 percent or one in 1061 procedures. A total of 348 patients had infections that were managed on an outpatient basis (Fig. 3). Forty of the patients who had infections required hospitalization (Fig. 4). The average hospital stay for these patients was 5.1 days. The length of stay varied from 1 day to 21 days. All infections resolved with local wound care or a combination of antibiotics and local wound care.

Forty-eight patients had an infection associated with an implant that was eventually removed. Forty-three patients had breast implants removed, and five patients had chin or other facial implants removed. There were no deaths attributable to infection.

Interestingly, Morello et al.[8] reported the same incidence of infection, 0.09 percent, for a frequency of one in 1145 procedures. Byrd et al.[2] reported six infections, an incidence of one in 886 procedures, or 0.11 percent. Natof's[10] study reported 10 patients with postoperative infections for an incidence of one in 1343 procedures or 0.074 percent.

Cardiac-Related Sequelae

Cardiac events occurred in 29 patients (incidence of one in 14,196 cases, or 0.007 per-

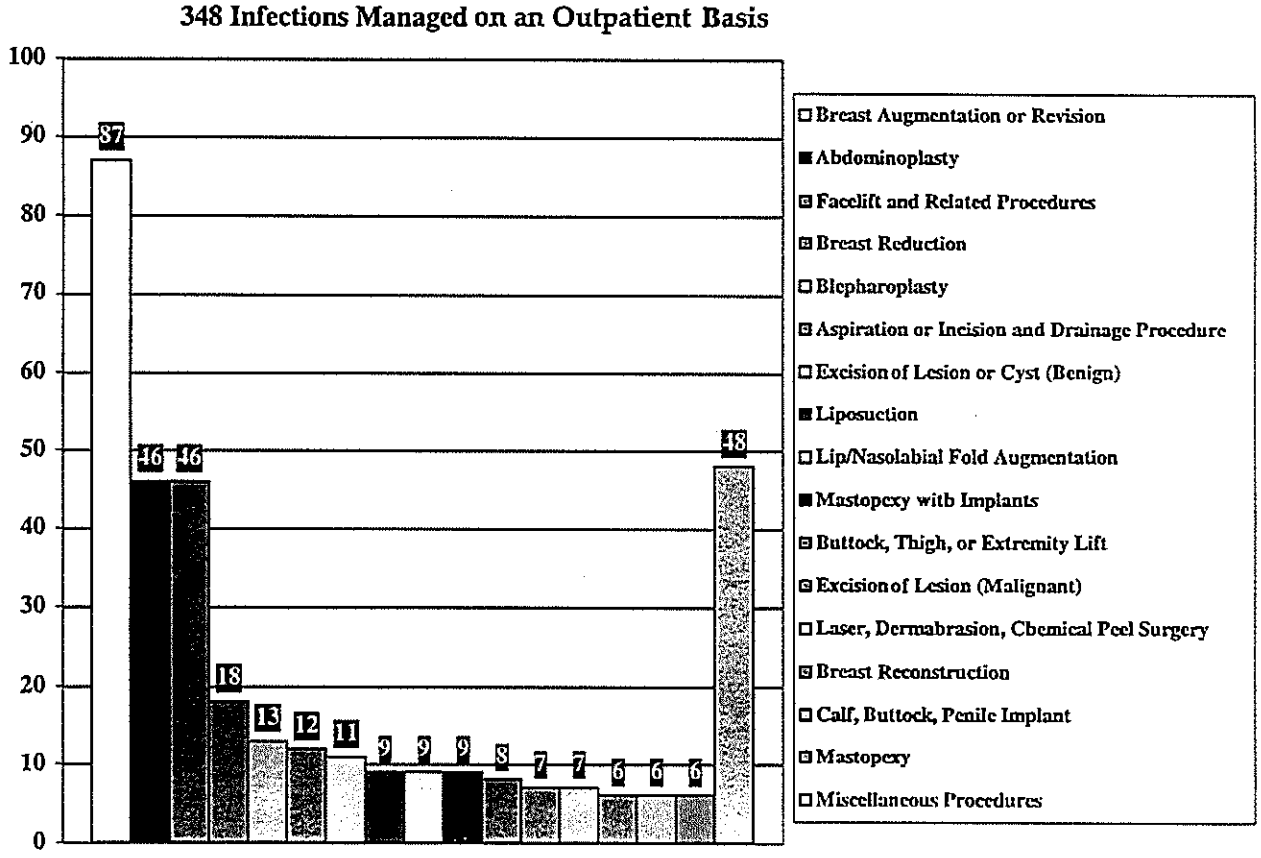

FIG. 3. Infections managed on an outpatient basis (n = 348).

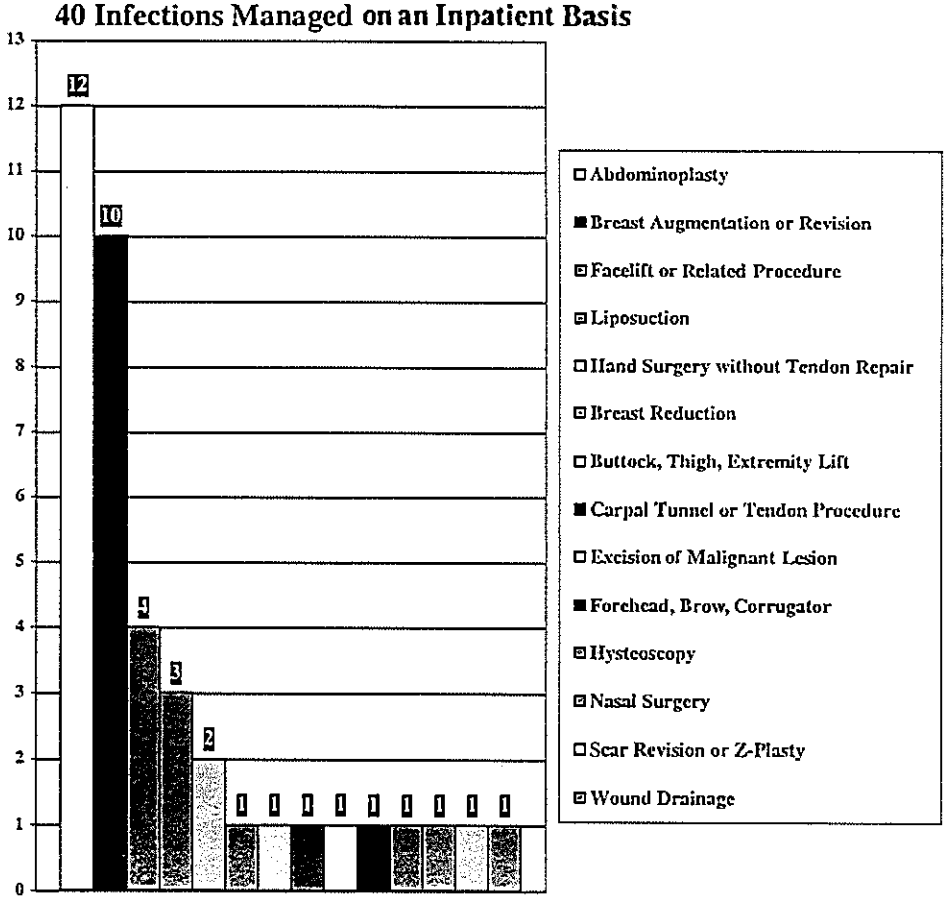

FIG. 4. Infections managed on and inpatient basis ($n = 40$).

cent). Twenty-seven patients had arrhythmias and two patients had cardiac arrests.

Of the two cardiac arrests, one patient became bradycardic, hypotensive, and unresponsive in the postoperative recovery room. A code was called and cardiopulmonary resuscitation, atropine, and epinephrine were administered. The patient was transferred to a hospital and admitted. Unresponsive and without spontaneous respiration, she was admitted to the cardiac care unit and placed on a respirator. After a 34-day hospital stay, the patient was discharged with some neurologic deficit.

The second patient was undergoing a face lift under intravenous sedation. It is believed that the patient had a myocardial infarction after becoming hypotensive intraoperatively. The patient was resuscitated, but immediately became bradycardic and was admitted to a hospital. She died after a 2-week hospital stay.

Fourteen of the patients with cardiac arrhythmias were hospitalized, with an average length of stay of 4 days (range, 0 to 34 days). Two patients were reported to have had chest pain in the early postoperative period that was determined to be due to anxiety (Fig. 5).

Blood Pressure Alteration

The current study showed that nine patients developed notable hypertension intraoperatively. All of these patients responded to medical management. Hypertensive episodes occurred in 0.002 percent of cases. One of these patients had their surgery canceled and was referred for medical evaluation.

Seven patients, or 0.002 percent of all cases performed, had notable hypotensive episodes. Five of these patients were hospitalized for an average period of 2.1 days. Two patients received a blood transfusion. All patients recovered without residual sequelae (Fig. 6). In the Morello et al.[8] article, hypertensive episodes represented 414 cases, or one in 968 procedures (an incidence of 0.1 percent). Intraoperative and postoperative hypotension occurred in 148 cases, or one in

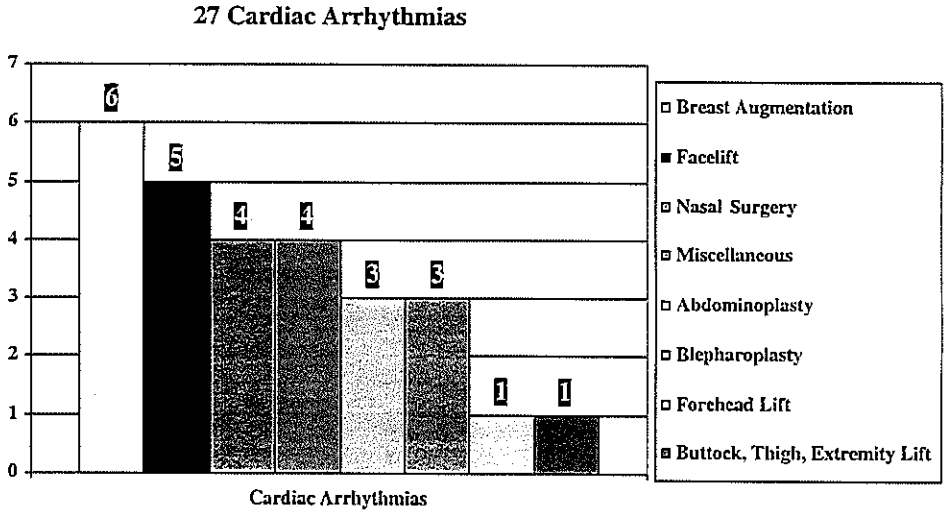

FIG. 5. Cardiac arrhythmias (n = 27). There were also two occurences of cardiac arrest.

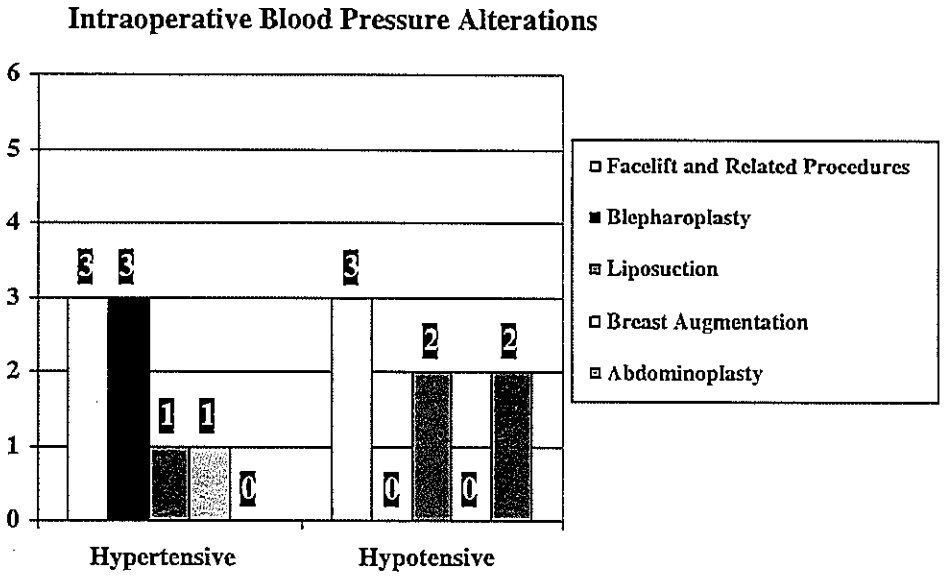

FIG. 6. Intraoperative blood pressure alterations (n = 15). One other patient experienced hypertension, but the operation was cancelled.

2707 procedures, an incidence of 0.04 percent.

Deep Vein Thrombosis or Pulmonary Embolism

All surgical patients are at some risk for the development of deep vein thrombosis in the lower extremities. The risk is increased for patients with a previous history of that condition, pulmonary embolism, or chronic venous insufficiency and for those with a family history of thrombotic syndromes. Other contributing factors include obesity, trauma, severe infection, polycythemia, central nervous system disease, malignancy, homocystinemia, history of radiation therapy, especially for pelvic neoplasms, and the use of birth control pills.[11,12]

There have been few reported studies on the frequency of deep vein thrombosis and pulmonary embolism associated with outpatient surgery. In the 2-year period monitored by the AAAASF quality improvement and peer review program, 31 patients developed deep vein thromboses or pulmonary emboli in 411,670 procedures (Fig. 7). This represents 0.01 percent of procedures performed, consistent with the report by Reinish et al.[13] As with the study by Morello et al., the Reinish group's study was conducted through a voluntary survey. The

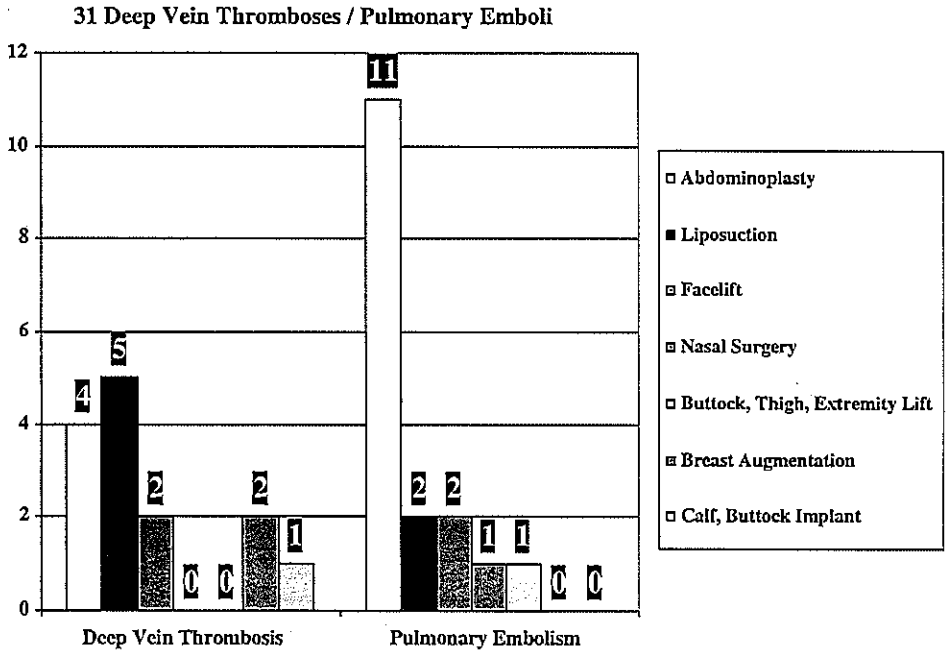

FIG. 7. Deep vein thromboses/pulmonary emboli (n = 31).

correlation of statistics with the mandatory AAAASF quality improvement and peer review Internet-based reporting system is significant.

Of these 31 patients with deep vein thromboses or pulmonary emboli, 14 patients had deep vein thromboses, of whom eight were hospitalized for management; six patients were treated on an outpatient basis. The average length of stay for those hospitalized for deep vein thromboses was 5.38 days (range, 2 to 12 days). There were no deaths associated with deep vein thromboses that did not eventuate in pulmonary emboli. All thromboses that did not result in pulmonary embolism resolved without additional sequelae.

The 17 patients who developed pulmonary emboli were hospitalized. The incidence of pulmonary embolism was one in 24,216 procedures, or 0.004 percent. The average length of stay for pulmonary emboli patients was 6.2 days (range, 1 to 11 days). Six deaths were reportedly due to pulmonary embolism. Four of the patients who died of pulmonary embolism had undergone an abdominoplasty. One of the aforementioned patients had undergone multiple procedures. The fifth patient who died had a pulmonary embolus 2 weeks after rhinoplasty. The procedure for the sixth patient who died was suction lipectomy of the abdomen using epidural anesthesia. The total amount of fat removed for the liposuction case was 3700 cc. All fatal pulmonary emboli occurred between postoperative days 2 and 14. In the remaining 11 patients, the pulmonary emboli resolved without residual sequelae.

The incidence of deep vein thrombosis was reported to be 0.3 percent in one large series of patients undergoing hip replacement.[14] Fatal pulmonary emboli occur in 0.1 to 0.8 percent of general surgery patients, 2 to 3 percent of patients undergoing elective hip replacement, and 4 to 7 percent of patients undergoing operative reduction of hip fracture.[14]

In a study of patients undergoing face lift surgery, Reinisch et al.[13] reported an incidence of thrombosis of 0.1 percent based on a survey of selected surgeons from the American Society of Plastic and Reconstructive Surgeons. In that study, 37 of 9493 face lift patients developed deep vein thrombosis (0.39 percent) and 15 patients developed pulmonary embolism (0.16 percent). Byrd et al.[2] reported no pulmonary emboli in their 5316 elective plastic surgery cases performed in an accredited outpatient plastic surgery facility.

Pneumothorax

Intraoperative pneumothorax has been reported as a complication in major surgical procedures about the chest wall when obtaining rib grafts, mobilizing chest muscle flaps, and performing chest wall reconstruction. In a re-

cent study, Osborn and Stevenson[15] surveyed 363 members of the California Society of Plastic Surgeons, requesting demographic data on each participant regarding the number of years that they were in practice and the number of breast operations performed per year. The remainder of the questions dealt with the incidence of pneumothorax encountered by surgeons when performing breast augmentation. Fifty percent of the surgeons responded (n = 181); their responses indicated that a total of 83 cases of pneumothorax had been encountered during breast augmentation in their practices.[15]

This study reports 19 cases of pneumothorax (Fig. 8). The incidence of pneumothorax was greatest for breast augmentation and augmentation-related procedures (n = 17). The other two cases of pneumothorax were diagnosed during an abdominoplasty and a breast reduction. In 17 patients, the pneumothorax was noted intraoperatively, and in two patients, it was diagnosed between postoperative days 1 and 4. Puncture of the pleura at the time of rib block occurred in seven patients, and an intraoperative pleural tear while cauterizing bleeders was the cause of pneumothorax for 11 patients. In one patient, pneumothorax was attributed to preexisting pulmonary blebs.

Osborn and Stevenson[15] discuss the potential for the occurrence of catamenial pneumothorax caused by endometrial implants on the lungs. They usually occur between 48 to 72 hours after the onset of menstruation and have been reported to account for 2.8 percent to 5.6 percent of all episodes of spontaneous pneumothorax in women.[15–21] There were no cases of catamenial pneumothorax reported in this study.

Twelve patients required chest tubes and were hospitalized. The average length of stay was 1.83 days (range, 1 to 7 days). The patient hospitalized for 7 days had bilateral pneumothorax with pulmonary edema that resolved. There were no deaths from pneumothorax in the 411,670 procedures performed.

Hyperthermia

Two cases of hyperthermia were reported. One case was managed with aspirin. The other case was a true malignant hyperthermia; the patient was managed with dantrolene sodium in the surgery center and transported to a hospital. The hospital stay lasted 1 day, and the patient was discharged without residual sequelae.

Deaths

In addition to the six deaths related to pulmonary embolism and the one death related to intraoperative hypoxia, another patient died on the first postoperative day, presumably from hypoxia related to sleep apnea. The patient was obese and had undergone a face lift. She died

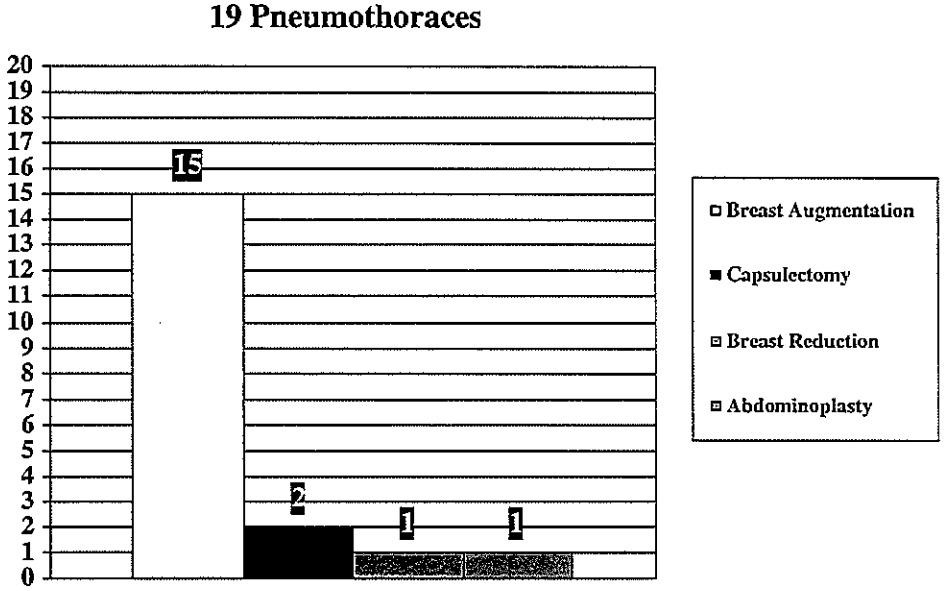

FIG. 8. Pneumothorax (n = 19).

in her sleep at home the evening after the operation.

The incidence of a patient dying after having an outpatient procedure was 0.002 percent, or one in 51,459 procedures. This compares favorably to the incidence in Morello et al.'s study,[8] which reported seven deaths in 400,675 procedures for an incidence of 0.0017 percent, or less than one in 57,000 procedures.

DISCUSSION

Comparison of data obtained through voluntary and mandatory reporting programs demonstrates close correlation in overall incidence of unanticipated sequelae, their occurrence by type, and postoperative deaths. It is important to note that of the eight deaths reported through the Internet reporting program, only two occurred in the intraoperative or immediate postoperative period. Most of the deaths were secondary to the development of pulmonary embolism, which can occur as the result of any surgical procedure, whether it is performed in a multispecialty free-standing outpatient facility, an office-based outpatient facility, or a hospital.

All patients with unanticipated sequelae who required hospitalization as the result of bleeding or infection were managed and discharged from the hospital with the sequelae resolved.

The AAAASF standards for accreditation of a surgery center require all surgeons to be certified by an American Board of Medical Specialties surgical board and to have core credentials in a hospital for all procedures that they perform in their surgery centers. It may be assumed that the surgical technique for any given procedure performed by a certified surgeon would be the same whether the procedure is performed in a hospital or a surgery center. The low incidence of intraoperative sequelae in this report demonstrates conclusively the safety of operation of outpatient surgery centers that are accredited by a recognized accrediting organization and staffed by American Board of Medical Specialties board-certified surgeons.

Additional broad based studies are being designed to identify areas to improve the delivery of outpatient surgical care. The first Internet model for collecting data on outpatient surgical outcomes, designed by the AAAASF, has added a new dimension to monitoring and evaluating patient care. Its current use and expansion will provide the needed data for further analysis of surgical outcomes. It is important to note that the analysis of outcomes will be more meaningful when reviewed in conjunction with a surgery center's compliance with accepted standards for operation.[22–24]

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REFERENCES

1. Rohrich, R. J., and White, P. F. Safety of outpatient surgery: Is mandatory accreditation of outpatient surgery centers enough? *Plast. Reconstr. Surg.* 107: 189, 2001.
2. Byrd, H. S., Barton, F. E., Orenstein, H. H., et al. Safety and efficacy in an accredited outpatient plastic surgery facility: A review of 5316 consecutive cases. *Plast. Reconstr. Surg.* 112: 636, 2003.
3. Iverson, R. A., Lynch, D. J., and the ASPS Task Force on Patient Safety in Office-Based Surgery Facilities. Patient safety in office-based facilities: II. Patient selection. *Plast. Reconstr. Surg.* 110: 1785, 2002.
4. American Society of Anesthesiologists. Office based anesthesia and surgery. American Society of Anesthesiologists, August 20, 2003. Available at: http://www.asahq.org/patientEducation/officebased.htm
5. Hoefflin, S. M., Bornstein, J. B., and Gordon, M. General anesthesia in an office-based plastic surgery facility: A report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications. *Plast. Reconstr. Surg.* 107: 243, 2001.
6. Singer, R. General anesthesia in an office-based surgical facility: A report on more than 23,000 consecutive office-based procedures under general anesthesia with no significant anesthetic complications (Discussion). *Plast. Reconstr. Surg.* 107: 252, 2001.
7. American Society of Plastic Surgeons and American Society for Aesthetic Plastic Surgery. Policy statement on accreditation of office facilities. Arlington, Va.: American Society of Plastic Surgeons. Available at: http://www.plasticsurgery.org/psf/psfhome/govern/officepol.cfm. Accessed April 24, 2001.
8. Morello, D. C., Colon, G. A., Fredricks, S., Nelson, R., and Singer, R. Patient safety in accredited office surgical facilities. *Plast. Reconstr. Surg.* 96: 1496, 1997.
9. American Association for Accreditation of Ambulatory Surgical Facilities, Inc. *AAAASF Standards and Checklist for Accreditation of Ambulatory Surgery Facilities.* Mundelein, Ill.: American Association for Accreditation of Ambulatory Surgical Facilities, 1999.
10. Natof, H. E. Complications associated with ambulatory surgery. *J.A.M.A.* 244: 11116, 1980.
11. Moreano, E. H., Hutchinson, J. L., McCulloch, T. M., Graham, S. M., Funk, G. G., and Hoffman, H. T. Incidence of deep vein thrombosis and pulmonary

embolism in otolaryngology-head and neck surgery. *Otolaryngol. Head Neck Surg.* 118: 777, 1998.
12. Iverson, R. E., and the ASPS Task Force on Patient Safety in Office-Based Surgery Facilities. Patient safety in office-based surgery facilities: I. Procedures in the office-based surgery setting. *Plast. Reconstr. Surg.* 110: 1337, 2002.
13. Reinisch, J. F., Rosso, R. F., and Bresnick, S. D. Deep vein thrombosis and pulmonary embolus following face lift: A study on incidence and prophylaxis. *Plast. Surg. Forum* 21: 159, 1998.
14. Avikainen, V., von Bonadorff, H., Patrio, E., et al. Low molecular weight beparin (enoxaparin) compared with unfractionated heparin in prophylaxis of deep vein thrombosis and pulmonary embolism in patients undergoing hip replacement. *Ann. Chir. Gynaecol.* 84: 85, 1995.
15. Osborn, J. M., and Stevenson, T. R. Pneumothorax as a complication of breast surgery. Submitted for publication.
16. Blanco, S., Hernando, F., Gomez, A., Gonzalez, M. J., Torres, A. J., and Balbrea, J. L. Catamenial pneumothorax caused by diaphragmatic endometriosis. *J. Thorac. Cardiovasc. Surg.* 116: 179, 1998.
17. Nakamura, H., Konishiike, J., Sugamura, A., and Takeno, Y. Epidemiology of spontaneous pneumothorax in women. *Chest* 89: 378, 1986.
18. Rossi, N. P., and Goplerud, C. P. Recurrent catamenial pneumothorax. *Arch. Surg.* 109: 173, 1974.
19. Mauer, E. R., Schall, J. A., and Mendez, F. L. Chronic recurring spontaneous pneumothorax due to endometriosis of the diaphragm. *J.A.M.A.* 168: 2013, 1958.
20. Shiraishi, T. Catamenial pneumothorax: Report of a case and review of the Japanese and non-Japanese literature. *Thorac. Cardiovasc. Surg.* 39: 304, 1991.
21. Van Schil, P. E., Vercauteren, S. R., Vermeire, P. A., Nackaerts, Y. H., and Van Marck, E. A. Catamenial pneumothorax caused by thoracic endometriosis. *Ann. Thorac. Surg.* 62: 585, 1996.
22. Bitar, G., Mullus, W., Jacobs, W., et al. Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4,778 consecutive plastic surgery procedures. *Plast. Reconstr. Surg.* 111: 150, 2003.
23. Weinstein, R. Nosocomial infection update. *Emerg. Infect. Dis.* [serial online] July 1998. Available at http://www.cdc.gov/ncidod/eid/vol4no3/Weinstein.htm.
24. Duncan, P. G., and Cohen, M. M. Are anesthetic complications predictable in day surgical practice? *Anesth. Analg.* 74: 876, 1992.

ATTACHMENT

B

health inventures.

Comparative Analysis of OBS Procedures versus ASC and Hospital Operating Rooms

Prepared for:

The Society of New York Office Based Surgery Facilities

408 Kenwood Avenue
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February 11, 2011

Limiting Conditions

This document has been prepared solely for The Society of New York Office Based Surgery Facilities and should not be relied upon for any other purpose. Unless required by law it shall not be provided to any third party without our prior written consent. In no event, regardless of whether consent has been provided, shall we assume any responsibility to any third party to which the report is disclosed or otherwise made available.

In developing project conclusions and recommendations, Health Inventures will be relying on a great number of assumptions, variables, estimates and judgments on matters over which Health Inventures will have no control, including without limitation, the economy in the market for client's center, economic conditions generally, the effects of competition, the legal and regulatory environment, limited and potentially incomplete information, and many others. The conclusions and recommendations are intended for use by The Society of New York Office Based Surgery Facilities; and Health Inventures makes no representations or warranties to The Society of New York Office Based Surgery Facilities that potential results will be attained.

Project Objective and Scope

The Society of New York Office Based Surgery Facilities (NYOBS) engaged Health Inventures (HI) to conduct a study, to determine the financial impact of surgical cases performed in an office-based surgical suite (OBS) versus those performed in ambulatory surgery centers (ASCs) and hospital surgical facilities.

This study was limited to OBS facilities in the state of New York.

Executive Summary

Based upon HI's survey results, there is a significant cost savings potential for certain surgical procedures to be performed in an OBS facility as opposed to more costly hospital operating rooms or ambulatory surgery centers. For the sub-set of procedures identified in this study, the potential savings range from $11M to over $24M. It should be noted, that this financial savings is based solely on the fourteen (14) most commonly performed procedures reported by the survey participants and does not include ALL of the surgical services they perform. It is HI's expectations that the savings would be much larger if all of the OBS procedures were included in this analysis.

In addition to the cost comparison information, the data shows that significant reimbursement policy variations exist within many commercial insurance carriers and between these carriers.

Approach

HI's approach consisted of conducting primary research with members of NYOBS as well as reviewing available literature that evaluated the cost differential of surgical procedures performed in an OBS versus those same procedures performed in an ASC or hospital operating room.

Methodology

Survey Development and Administration
HI and NYOBS representatives designed an eight-question survey to assess the insurance reimbursement environment for OBS facilities and to gather case volume and gross facility fees, which included supplies, for the most common surgical procedures performed in OBS facilities. All data was self-reported.

In addition to the procedure data, the survey also sought to identify basic demographic information from the respondents such as the medical specialties represented in OBS facility and facility zip code. The survey was sent to the OBS facility members of NYOBS and was administered during a twenty-four (24) hour period using web-based survey provider, Survey Monkey.

Data Analysis
After receiving the survey responses, HI downloaded the raw data from Survey Monkey and analyzed the results. HI identified the specialty mix of respondents, their geographic location and the type, volume and cost of the most common procedures they reported to perform in their OBS facilities. HI also compiled and analyzed the data describing the respondent's experience with the major insurance plans serving New York State.

Once our target data was gathered, HI applied average gross charges and net charges from comparable ASCs and hospitals to illustrate the relative costs of performing the same procedures in different settings. Due to time and data limitations, the ASC and hospital data utilized for comparison was confined to facilities that are geographically proximate, but not in the exact locales as the target OBS locations. This has the potential to distort the calculated cost differentials; however, HI does not believe the differences will be meaningful to the study since the cost differentials would likely only be magnified if an exact zip code correlation was used since many of these OBS locations were in Manhattan.

Results

Respondent Specialty Mix

During the one-day period in which the survey was open, HI received twenty (20) responses to the survey from a cross section of facilities. These responses represented input from twenty OBS facilities which likely include information for more than one physician per facility.

Table 1a: Respondents by Specialty

Count	Percent	Specialty
4	20%	Podiatry
3	15%	Plastic Surgery
3	15%	Gastroenterology
3	15%	OB/GYN
2	10%	Dermatology
2	10%	ENT
1	5%	Ophthalmology
1	5%	Orthopedic Surgeon
1	5%	Pain Management
20		

Table 1b: Respondents by Geography

Count	Percent	Area-Zip Code
13	65%	Manhattan
3	15%	Long Island North Shore
1	5%	Governor's Island
1	5%	Kings
1	5%	Staten Island
1	5%	Not Disclosed
20		

Payer Experience

In reporting their experience with how commercial insurers covered facility fees for OBS, respondents cited that they currently receive payment from fewer insurance carriers than previously.

Table 2: Current & Historical View of Payers that "Typically Reimburse" for A Facility Fee for OBS

Payer	Current	Previously
Aetna	2	6
CIGNA	9	11
Empire Blue Cross/Blue Shield	1	3
Excellus	0	1
Health Insurance Plan of NY (HIP)	0	1
Health Net	5	8
Emblem Health	0	0
GHI	1	4
MVP	0	0
Oxford	2	9
United	5	11

*Three respondents wrote in that Union Plan 1199 reimburses for an OBS facility fee..

Surveyed respondents also identified the commercial payers that would never reimburse for an OBS facility fee. A comparison of the data in Table 3 suggests that there has been an increase in the participant's experience of payers that never reimburse for OBS facility fees.

Table 3: Current and Historical View of Payers that "Never Reimburse" for OBS facility fees

Payer	Current	Previously
Aetna	12	5
CIGNA	5	1
Empire Blue Cross/Blue Shield	12	6
Excellus	10	7
Health Insurance Plan of NY (HIP)	12	8
Health Net	9	3
Emblem Health	13	9
GHI	14	7
MVP	9	6
Oxford	13	2
United	8	1

OBS Procedures

Procedures in the fields of gastroenterology, podiatry, and pain management represented the majority of the procedures performed in OBS facilities. The procedures selected for inclusion in the evaluation represent the most common OBS facility procedures observed. Respondents were only asked to identify the most common procedures performed and only the most common procedures within those responses are described within Table 4.

HI sampled 29,214 ASC cases performed in ASCs in the northeast U.S. to compare to the procedures performed in OBS facilities.

As evidenced in Table 4, ASC and hospital charges are significantly higher than OBS facility fees across all services. The cost differential for arthroscopic orthopedic surgeries was shown to have the greatest charge differential. These procedures cost $6,236 more to perform in an ASC than an OBS and $13,557 more to perform in a hospital than an OBS. Note that because the figures are based on ASC charges in a much broader geographic area than the comparable OBS facilities, they are likely to significantly underestimate the actual charges in ASC's in comparable zip codes to the OBS facilities. Note that 65%of the OBS facilities surveyed are in Manhattan.

Table 4: Most Common Procedures Performed By Surveyed OBS facilities

Procedure	Specialty	Instances	Gross Facility Fee[a]	ASC Gross Facility Fee[b]	Local Hospital Gross Facility Fee
EGD – 43239	Gastroenterology	1,700	$500	$2,787	$6,133[c]
Colonoscopy – 45380	Gastroenterology	1,350	$550	$2,787	$5,494[c]
Colonoscopy – 45385	Gastroenterology	1,080	$600	$4,692	$5,494[c]
Bunionectomy – 28296	Podiatry	980	$1,250-$3,150	$5,815	$5,500[a]
EGD – 43248	Gastroenterology	600	$500	$4,939	$6,133[c]
Hammertoe Correction – 28285	Podiatry	600	$900	$12,125	$5,500[a]
Arthroscopic Shoulders & Knees	Orthopedic Surgery	600	$2,500	$8,736	$16,057[c
Colonoscopy – 45378	Gastroenterology	550	$500	$2,436	$5,494[c]
Cervical Pain Injection – 62310	Pain Mgt	400	$600	$1,838	$1,909[d]
Lumbar Facet Injections – 64490	Pain Mgt	300	$750	$4,403	
Epidural Pain Block – 62311	Pain Mgt	200	$600	$2,003	$1,767[d]
Trigger Point Injections – 20552	Podiatry	150	N/A	$4,721	$929[d]
Adjacent Tissue Transfer – 14060	Plastic Surgery	129	$1,000-$2,450	$4,142	
Adjacent Tissue Transfer – 14040	Plastic Surgery	111	$1,000-$2,450	$5,674	

(a) Provided by surveyed facilities
(b) Average ASC gross facility fees for 5 ASCs within 100 miles of Manhattan. Provided by Health Inventures, LLC.
(c) Hospital facility fees for provided by newchoicehealth.com. Hospital gross fees based on a sample of charges from 16 hospitals in New York City.
(d) Hospital facility fees provided by a single hospital within 50 miles of Manhattan. Provided by Health Inventures, LLC.

Cost of Care by Facility Type

Gross OBS facility fees represent charges for OBS services which may not necessarily be reimbursed currently. Contractual discount arrangements with insurance carriers, or lack thereof, as well as refusal of payment by insurance carriers may result in a partial or complete write-off of the gross facility fee. It is significant to note that the average ASC net fees, representing actual reimbursement to ASCs, are higher than OBS gross fees for most surveyed procedures. Under the current charge structures, in-OBS facility fees will never be comparable to ASC or hospital costs.

As noted above, these fees may be significantly underestimated due to difference in locale of the ASC's compared to the OBS facilities.

Table 5 below, shows the "net fees" paid to the ASCs are higher than the "gross fees" charged OBs facilities in nearly every instance. It would cost insurers and employers $11.0 million if these OBS cases were performed in an ASC setting. Many of the cases performed in some of these OBS facilities are not listed because they are not among the most common procedure performed in the facilities. Only the fourteen (14) most common procedures are described and these most common procedures only represent eleven (11) of the twenty (20) respondent OBS facilities. The best sample of data is for gastroenterology procedures since there are a limited number of high-volume procedures performed by gastroenterologists in their OBS facilities. Additionally, in Manhattan, which represents 65% of the OBS facilities, there are currently only 10 non-hospital affiliated ASC's. Therefore, it is unlikely that these cases could be moved to ASC's, but rather would be performed in hospitals.

Table 5: ASC Surgery Cost of Procedures Performed in Surveyed OBS facilities

Procedure	Specialty	Instances	Average ASC Net Fee[(a)]	Costs of Moving Same Cases to ASCs
EGD – 43239	Gastroenterology	1,700	$888	$1,509,600
Colonoscopy – 45380	Gastroenterology	1,350	$926	$1,250,100
Colonoscopy – 45385	Gastroenterology	1,080	$1,089	$1,176,120
Bunionectomy – 28296	Podiatry	980	$1,909	$1,870,820
EGD – 43248	Gastroenterology	600	$692	$415,200
Hammertoe Correction – 28285	Podiatry	600	$2,322	$1,393,200
Arthroscopic Shoulders & Knees	Orthopedic Surgery	600	$2,971	$1,782,600
Colonoscopy – 45378	Gastroenterology	550	$888	$488,400
Cervical Pain Injection – 62310	Pain Mgt	400	$618	$247,200
Lumbar Facet Injections – 64490	Pain Mgt	300	$1,441	$432,300
Epidural Pain Block – 62311	Pain Mgt	200	$587	$117,400
Trigger Point Injections – 20552	Podiatry	150	$871	$130,650
Adjacent Tissue Transfer - 14060	Plastic Surgery	129	$935	$120,615
Adjacent Tissue Transfer - 14040	Plastic Surgery	111	$1,242	$137,862
		TOTAL COST IN ASCs		**$11,072,067**

(a) Net ASC facility fees for 5 ASCs within 100 miles of Manhattan. Provided by Health Inventures, LLC.

HI also compared the cost differential for shifting the cases performed in OBS suites to the hospital setting and found that the site of service cost for these same cases would be over $24M. Table 6 on the next page illustrates this cost shift potential.

Table 6: Hospital Surgery Cost of Procedures Performed in Surveyed OBS facilities

Procedure	Specialty	Instances	Average Hospital Net Fee[(a)]	Costs of Moving Same Cases to Hospitals
EGD – 43239	Gastroenterology	1,700	1,910	$3,247,000
Colonoscopy – 45380	Gastroenterology	1,350	1,739	$2,347,650
Colonoscopy – 45385	Gastroenterology	1,080	2,679	$2,893,320
Bunionectomy – 28296	Podiatry	980	5,078	$4,976,440
EGD – 43248	Gastroenterology	600	3,872	$2,323,200
Hammertoe Correction – 28285	Podiatry	600	5,131	$3,078,600
Arthroscopic Shoulders & Knees	Orthopedic Surgery	600	5,006	$3,003,600
Colonoscopy – 45378	Gastroenterology	550	1,447	$795,850
Cervical Pain Injection – 62310	Pain Mgt	400	1,076	$430,400
Lumbar Facet Injections – 64490	Pain Mgt	300	1,100	$330,000
Epidural Pain Block – 62311	Pain Mgt	200	883	$176,600
Trigger Point Injections – 20552	Podiatry	150	690	$103,500
Adjacent Tissue Transfer – 14060	Plastic Surgery	129	2,816	$363,264
Adjacent Tissue Transfer – 14040	Plastic Surgery	111	2,915	$323,565
		TOTAL COST IN HOSPITAL		**$24,392,989**

(a) Net hospital facility fees from HI affiliate within 50 miles of Manhattan. Provided by Health Inventures, LLC.

Literature Review

As a part of our analysis, HI conducted a brief review of other primary research that was conducted to evaluate the site of service cost differential for OBS versus ASC and hospital-based procedures. Based upon our review, we did not find a large body of research conducted on this topic, however, one study was identified that demonstrated similar results to our survey.

In the February 2007 edition of Laryngoscope, the authors reported on a comparative analysis of hospital operating room versus OBS injection laryngoplasty (IL). In their research on 158 surgeries performed (108 – hospital operating room, 50 – OBS) from 1998 to 2005, the authors found that the cost of an IL procedure performed in a hospital operating room was $2,009 more than the same procedure performed in an OBS. The authors further detailed that the reimbursement differential "was preserved across the various insurance types examined".

ATTACHMENT

C

MANAGED Care

Paying More Than You Should For Outpatient Procedures?

New accreditation standards make it possible to do in physicians' offices what's now being done in hospitals — at significant savings

Rock Rockett, PhD

Recent data from a large New York health plan show that about 85 percent of colonoscopies for metropolitan New York members are performed in physicians' offices. That's about 26,000 gastrointestinal procedures every year per 1 million health plan members under age 65. With about 9.1 million total covered lives under age 65 in the NYC area for this company, that's 236,600 diagnostic colonoscopies per year. These GI physicians are paid an average of $450 per procedure with no additional facility fee, since the procedures are mostly performed in physicians' offices.

It's a different story for a major payer in Chicago. Instead of 85 percent of GI procedures being performed in lower cost office settings, 78 percent are performed in hospital out-patient departments (HOPDs). And its rate per million members is closer to 40,000 annually. In Chicago, GI doctors are paid about $330 on average for their procedures plus facility fees for HOPD or ambulatory surgery center (ASC) charges.

With facility fee charges ranging from about $2,000 to $6,000 per procedure, depending on all the normal factors affecting HOPD fees, the potential savings from shifting these high volume procedures from higher cost HOPDs to accredited physician offices is substantial. With a difference of $1,000 per procedure, on average, the savings could be as much as $32 million per year, assuming that roughly 80 percent of the colonoscopies could be shifted to the office setting.

Accredited by whom?

In New York and about 15 other states, physicians performing diagnostic colonoscopies under intravenous sedation, or any other procedure under IV sedation, are required by new state laws to be accredited by 1 of 3 national health care accreditation agencies. Accreditation of physician offices for office-based surgery can be achieved by working with the Joint Commission, the American Association of Accreditation for Ambulatory Surgery Facilities, or the Accreditation Association for Ambulatory Health Care. All three accreditation agencies have programs to survey physician offices to be sure that the offices meet their high

standards for patient safety, including infection control, review of credentials for medical professionals, ability to respond to instances of cardiac arrest, proper evacuation procedures for staff and patients in the event of a fire or other emergency, and more.

A relatively small percentage of physician offices nationally have achieved accreditation for office-based surgery, but the numbers are growing. In New York, about 900 physician offices have attained accreditation as a result of the requirement put into effect by the State Department of Health in July 2009. Typically, the drivers for physicians to take the step of going through the accreditation process and having the policies and procedures in place to maintain their accreditation status thereafter are financial incentives from health plans to do so and state health department or medical board requirements to ensure patient safety.

Accreditation for office-based surgery raises costs for physicians and adds to their office work load because of the processes that must be put in place to comply with the standards on patient safety, infection control, medication reconciliation, quality improvement, and so forth. All of these are good provisions and important requirements for office-based surgeons and GI physicians to follow, but the cost of compliance must be completely borne by the physicians.

Specialties that are appropriate for office-based surgery are not only gastroenterology but also urology, plastic and reconstructive surgery, gynecology, vascular surgery, pain management, podiatric surgery, and oral and maxillofacial surgery practices, all of which may perform surgical or endoscopic procedures in their offices.

How can health plans proactively encourage physicians to become accredited and shift high volume outpatient procedures from higher cost settings to accredited office settings?

A solution!

A few health plans are embarking on programs to pay accredited office-based surgery providers a global fee or an enhanced fee to cover the additional costs of doing the procedures in-house. These innovative programs appropriately compensate physicians for their increased equipment and labor costs.

Anthem Blue Cross Blue Shield of Virginia has implemented such a program and is having success in driving more and more outpatient procedures to accredited office settings. Other BCBS plans are designing programs to provide financial incentives for gastroenterologists to become accredited and perform procedures in their accredited offices. And other major national payers contract with accredited office-based surgery providers in some states in much the same way that they contract with ambulatory surgery centers.

Health plans must first assess their data on high volume outpatient procedures by place of service to determine their potential for savings. Considering just a handful of GI procedure codes is a good place to start, such as determining the relative incidence of the following procedures by place of service (HOPD, ASC, or office):

43239	Upper GI endoscopy, biopsy
45378	Diagnostic colonoscopy

45380	Colonoscopy and biopsy
45385	Lesion removal colonoscopy

In all likelihood, about 95 percent of endoscopic GI procedures will have one of these four procedure codes. With information on these procedures by place of service, health plans can determine potential cost reductions.

Effect on plan, members?

Health plans will no doubt reduce their costs of outpatient surgical procedures by implementing an effective program to encourage specialists to become accredited for office surgery or endoscopy. The savings will range considerably based on the provider agreements that plans have in effect with hospitals and ASCs. An added plus is that members will view office endoscopy more favorably than having the same procedure in an HOPD and will find it more convenient to have their all-important colon cancer screening procedure performed in the less intensive setting of a physician's office. With lower costs, increased convenience for members, and greater rates of colon cancer screening being done, the overall benefits to plans, members and providers are easy to recognize.

Rock Rockett, PhD, is CEO of Validare, a company that works to improve patient safety and increase savings in office-based surgery settings. He can be reached at rrockett@validare.com or at 888-934-4321.

First, thank you for the opportunity to comment on this. Let me explain who I am. My name is Domenico Leuci. I'm an Ob/Gyn in Binghamton. I have a solo private practice, with a part time nurse practitioner. I definitely don't meet the definition of "mega practice". However, I might be considered an enhanced physician practice. It's not completely clear to me what that definition is. I imagine that hospital systems want it to include everyone that could potentially compete with them. I provide ultrasound services to my patients; I perform non-invasive procedures under local anesthesia; I perform moderate complexity lab tests; and I provide prenatal testing. Granted these are all small things compared to some of the services that occur in larger practices, but they are competitive to hospital provided services, and I fear the hospital lobbyists will try to limit all of these.

We are at an important time in healthcare, but I'm afraid we are heading in the wrong direction. All of this is because of cost, and the notion that we must decrease it. The strategy for the last few years has been to centralize care at regulated facilities (hospitals). The belief has been that this will allow the federal and state governments, along with private insurers, to ensure quality while keeping costs down. Hopefully you've read the Time magazine article "Bitter Pill" that was published a few weeks ago. I can't cover the breadth of that article in this brief email, but I think the author made it convincingly clear that hospitals are not even trying to keep healthcare costs down. In fact, it is their thirst for profit (despite their inaccurate "not for profit" tax designation) that has lead to the overinflated costs.

Likewise, it is incorrect to assume that hospital-based services, and overly regulated office services, will lead to better care. This is merely propaganda disseminated by hospitals to make it impossible for private physicians to provide competitive services. Physicians are the ones who train for 10-12 years, accrue 6 figures worth of debt, and show up for emergencies at 3 in the morning. We have to stop vilifying physicians who are merely trying to provide services to their patients. Our office based services are convenient for patients, less costly than hospital services, and provide equal (if not better) care. Limiting patient access and raising costs either by prohibiting certain services or increasing the bureaucracy to provide services will be a disservice to patients, as well as physicians.

Lastly, on the topic of Certificate of Need, it's simply a restriction of free trade. If we as a state and country feel it's necessary though, then we need to restrict hospitals from overly aggressive hiring practices. In many parts of the state, in certain specialties, we have a glut of providers. Hospitals have realized what specialties can generate revenue for them, and they are hiring more than are needed. If hospitals want to limit what physicians can do, then it's only fair to let physicians protect our right to practice without undue competition.

Thank you.

UB|MD
PHYSICIANS' GROUP

March 19, 2013

Karen Lipson
Director
Division of Policy
Joan Cleary Miron, MPH
Director
Division of Primary Care Development
New York State Department of Health
phhpccplanning@health.state.us

Dear Ms. Lipson and Ms. Miron:

I am writing on behalf of the Management Council of UB|MD, the faculty practice plan associated with the State University of New York at Buffalo, in reply to your specific questions about the impact of group practices on medical care. UB|MD is a multispecialty group practice of more than 500 faculty physicians and other health care providers located in Buffalo with offices throughout Western New York.

One specific and important benefit of our faculty practice plan is that it has greatly enhanced access to and quality of care in Western New York. A multispecialty group practice can provide comprehensive treatment for a broad array of disorders, and care by primary care practitioners and specialists can be much more readily coordinated in a single group than can disparate practices containing different specialties. Since academic physicians generally are at the forefront of research and practice, we are very familiar with data on the cost effectiveness as well as the efficacy of new treatments. Indeed, physicians in academic practices are often the very physicians who participate in national guidelines writing committees, including appropriate use criteria. Ready availability of specialists in the same group provides immediate

consultation to our primary care practices in the region to facilitate decisions about whether or not a specialist should see the patient. As an integrated practice, we are able to provide more outreach to underserved areas. As one example, the Psychiatry Department practice plan oversees a program to provide child psychiatry input to patients of pediatricians and family physicians throughout the state, regardless of finances. Clinicians in all departments coordinate care closely with public agencies, other practices, and third party initiatives. In fact, a new collaboration of UB|MD, two of the major general hospitals, and an insurance company is developing a network that includes physicians from all practices who are committed to providing peer-reviewed evidence based care to urban and rural areas.

Like all academic practice plans, the primary goals of UB|MD are to support the academic mission of the School of Medicine and improve the quality of care in the region and nationally. With regard to the former, an efficient practice plan provides funding as well as clinical sites for teaching and research. Oversight by a Governing Board elected from faculty physicians ensures that the practice plan promotes the academic missions of the School. The practice plan not only facilitates the operations of the School of Medicine; it is essential to them.

For-profit urgent care centers that have emerged in the region recently have not noticeably improved access to or quality of care and generally do not appear to reach underserved populations as they are not located in areas that are easily reachable by those populations. In addition, they promote convenience for a particular minor problem, but not continuity of care. Three of the busiest emergency departments in the region, namely Erie County Medical Center (ECMC, a level 1 traUBa center), Buffalo General Medical Center, and the Western New York VA Medical Center, are staffed by UB|MD physicians. ECMC's Comprehensive Psychiatric Emergency Program (CPEP), in which medical care is provided by UB|MD physicians, remains the busiest such service in New York State. Offering urgent care and outreach programs linked to these emergency departments, some of them funded by grants from local agencies, leads to decompression of these emergency services and promotes continuity of care because physicians in the same group follow the patients after an urgent care visit. Quality of care oversight at UB|MD -affiliated urgent care services is included in the rigorous quality improvement functions of the departments. Anecdotally, it is not clear that the same oversight occurs at for-profit urgent care centers.

Our ability to offer advanced diagnostic imaging through our Departments of Nuclear Medicine, Radiology, Orthopedics and Neurosurgery, among others, has greatly enhanced access to care and patient satisfaction because patients do not have to make a separate appointment and travel to remote sites to receive appropriate imaging services. Quality of care has been enhanced because imaging can be interpreted on the spot by the team caring for the patient, including clinicians who will be providing the appropriate intervention. Costs are reduced by avoiding additional imaging sites with more overhead costs.

Imposing CON and other regulatory requirements on large physician practices would impose a bureaucratic burden that would necessitate physician time being allocated to responding to demands for information, decreasing time available to see patients, as well as additional

personnel to meet paperwork requirements, either increasing the cost of care or reducing access as front line staff are reassigned to meet licensing requirements. It is difficult to understand how any gain would offset such costs.

Faculty practice plans such as UB|MD are completely consistent with the spirit of New York's Education Law because under Section 1412 of the NYS Not-for-Profit Corporation law, all members and directors of faculty practice plans must be licensed to practice medicine in the State of New York. There is no threat of non-licensed, non-medical professionals directing or operating a faculty practice corporation under New York State law. We support current NY laws that effectively ban the corporate practice of medicine. Such a ban ensures that professional services are provided by licensed professionals without undue influence from unlicensed third parties who are not subject to the same professional responsibility requirements as licensed professionals.

Decisions about evidence-based technologies and specialized services are made after extensive review by UB|MD committees. Third party payers in the region already rely on consultants to decide whether or not to cover these services. The need for an additional group (and its attendant costs and delays) to review such activities therefore is not apparent.

I hope that I have addressed the questions you raised. Please let me know if I can provide any additional information.

Sincerely,

Steven L. Dubovsky, M.D.
President
UB|MD Management Council
[redacted]

FLHSA
The community health fulcrum

March 22, 2013

Karen Lipson, Director
Division of Policy
Office of Health Systems Management

Joan Cleary Miron, Director
Division of Primary Care Development
Office of Primary Care
NYS Department of Health

RE: Physician Practices and Certificate of Need

Dear Ms. Lipson and Ms. Miron:

This is in response to your February 25 letter requesting comments on what criteria the Department and the Public Health and Health Planning Council should use in evaluating the effect of surgical care, radiation therapy, imaging and other high technology services in physician practices and facilities.

We understand from our listening to the discussions of the Planning Committee that the policy options being considered to "level the playing field" between Article 28 facilities and physician practices/facilities is whether to institute CON oversight on high technology services by the physician practices, or to de-regulate such services provided by hospitals or other Article 28 providers. Based on our experience in the Finger Lakes region, we would urge you to move toward the position of overseeing all such services.

As you know, we have in the northern part of the Finger Lakes region reviewed for over a decade all technology applications, irrespective of auspices, through the Community Technology Assessment Advisory Board (CTAAB) process. This perhaps has provided unique insights on the questions you and the Council are asking. We will try to illustrate some of those insights in our responses to your questions.

1. *To what extent are enhanced physician practices affecting access to care, quality of care, patient satisfaction, disparities, costs or population health in your community? If so, how?*

In our urban areas, such practices are limited to specialty services, "urgent care" centers, and freestanding radiology centers. This region does not have "mega" practices with the exception of the faculty practice associated with the University of Rochester. Except as discussed below, their effect on access, quality, satisfaction, disparities, costs, and population health are similar to the effects of other physician practices. They do seem more able than other physician practices to successfully recruit new physicians.

Finger Lakes Health Systems Agency
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In our more rural areas, many enhanced practices have the effect of directly competing with the rural hospitals on ancillary testing, often to the detriment of the hospital's finances and services quality by drawing volume from the hospital service. This affects the hospital's ability to provide services to all patients without regard to payer or ability to pay.

On the other hand, some enhanced specialty practices represent a mechanism to provide services in rural areas that no single rural hospital could support financially or with quality due to small demand.

2. *Are enhanced physician practices affecting the operations or finances of your organization or your organization's members? If so, how?*

Not applicable.

3. *Are facilities or enhanced physician practices that provide urgent care affecting access to care, quality of care, patient satisfaction, disparities, costs or population health in your community? Are they affecting your organization or your organization's members? If so, how?*

In recent years, the Rochester area has experienced an explosion in development of "urgent care" centers (there is need to distinguish between urgent care and office-based after hours services). Some of the new urgent care centers are developed by individual practitioners or small groups; others are developed by business corporations, including organizations from outside the region. Initially, local payers encouraged such development as being less expensive than Emergency Departments; presently, Finger Lakes HSA, local payers and the Monroe County Medical Society have sponsored a television campaign that encouraged patients to "call their physician first" for minor illnesses to reduce ED overcrowding.

https://www.excellusbcbs.com/wps/portal/xl/!ut/p/b0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOJDQoNMfMw9jAzcPQPMDTxNwnyCLc0DjAyCjfQLsh0VAfw_Qe0!/?WCM_PORTLET=PC_Z7_TUR4L7H20GIP70I4VLS97P2020000199_WCM&WCM_GLOBAL_CONTEXT=/wps/wcm/connect/default/excellus/our+company/news+room/news+releases/excellus+corporate+news/exc-pr-corp-29nov11-excellus+bcbs+-+health+groups+target+potentially+avoidable+er+visits

Studies in our area have shown that growth of urgent care centers has led to a decrease in visits to primary care practitioners, perhaps leading to the detriment of continuity of care and promotion of preventive services, and decreasing PCP volumes with its financial impact on primary care offices.

All area hospitals have "Fast-track"-type options attached to their Emergency Departments. A number of existing urgent care centers are institutionally sponsored and help meet care needs of all populations. Examples are the After-hours clinics of Lifetime Health, a subsidiary of Excellus BCBS, the Unity Health System's Walk-in Care Center located in inner-city Rochester in the former ER of the St Mary's Hospital and a freestanding urgent care center in a less urbanized area in Monroe County operated by Lakeside Hospital (Brockport). However, the

recently-developed non-institutional facilities generally do not accept Medicaid patients and are all located in well-to-do suburbs and thus increase access only for those who are best able to access care already. A map of all existing urgent care centers is attached. A list of all such centers is maintained by the Monroe County Medical Society at http://www.mcms.org/contents/Resources/Forms%20%20for%20Download/After%20Hours%20Guide.version_5.pdf.

CTAAB intervened in development of one Rochester-area urgent care center sponsored by a Buffalo organization that desired to install a CT scanner. As there was no area-wide need for additional CT capacity, the facility was advised a scanner would likely not be approved (and had questionable appropriateness); the center was developed without the scanner.

4. *Are enhanced physician practices that provide office-based surgery affecting access to care, quality of care, costs, patient satisfaction, disparities, or population health in your community? Are they affection your organization or your organization's members? If so, how?*

Although CTAAB reviews applications for office-based surgery, it often does not hear of developments in that area. Some years ago, CTAAB reviewed a number of proposals seeking to expand capacity to perform colonoscopy, to avoid overdevelopment based on new volume due to changes in recommendations for need for colonoscopy. There have not been any recent requests for such capacity, however, as most colonoscopy in the Rochester area is now done in office settings.

While this question is limited to office-based surgery, your general comments in the memo concerned all extensions of services under the auspice of physician practices. CTAAB has studies and reviewed a number of other "high tech" services provided by physician organizations. Sleep diagnostic services ("sleep labs"), for instance, are provided in this region by three hospitals (and a few other hospitals via vendors), an out-of area corporation, and a few private physician practitioners.

5. *Are enhanced physician practices that provide advanced diagnostic imaging (e.g., CT scans, PET scans, and MRI) affecting access to care, quality of care, patient satisfaction, disparities, costs, or population health in your community? Are they affection your organization or your organization's members? If so, how?*

Finger Lakes Health Systems Agency surveys all CT, MRI and PET providers (institutional and free-standing) in the region annually, and reviews requests for added advanced imaging capacity based on that information. We obtain greater than 95% participation in these voluntary surveys. Copies of reports on CT and MRI with CY 2011 data are attached. The surveys allow us to assure a) that hospitals have sufficient capacity to image inpatients and ED patients, who cannot get scans elsewhere; and b) assure that there is adequate but not excess capacity and access for such scans.

In the urban areas, there are freestanding (physician sponsored) imaging centers. These centers provide alternatives to hospital-based imaging, but do not greatly enhance geographic access to imaging. They do not (are not allowed to) provide services to Medicaid patients, and provide minimal access to self-pay patients. Most provide extended hours of service. For the most part, they have maintained up-to-date equipment, but that is not universally true; for instance, the only remaining 0.3 Tesla MRI in the region is a freestanding unit.

This region does not have any free-standing units in the rural areas. On two occasions, we have recommended against applications for such units because of the lack of community need for the proposed capacity and recognition of the negative impact (lower volume, lower income) of the proposals on existing (hospital-based) services.

All freestanding units in the region are radiologist-owned. On three occasions, CTAAB has reviewed applications for imaging equipment from non-radiologist physicians, but have recommended against those applications. Two of those applications were from orthopedists, while the third was from a cardiology group. Thus, our sense is that due to the ability to review imaging projects from all auspices, this region has been able to avoid the self-referral utilization experienced by other areas.

Universal review of imaging proposals has also provided assurance of quality of care. In one proposal, for instance, an orthopedist-sponsored proposal would have had radiologists "read" the resulting scans. However, in the course of the review it was revealed that radiologists would not be available on site to monitor technical quality, nor to supervise administration of contrast media during procedures.

Even with prior or concurrent approval programs, experience has shown that imaging indications are subject to interpretation, and that a scanner installed is a scanner utilized. This is illustrated in a study done by FLHSA for Excellus of high-tech services in Upstate NY. Although now dated, it shows in many services a strong correlation between capacity and use. A copy of the study report is attached; note particularly the chart regarding MRI services (page 9) and that regarding CT scanning (page 6). A fully used MRI scanner in this region represents nearly 50¢ per member per month in premiums, so there is sensitivity in this region that excess capacity is not a free good.

6. *Are enhanced physician practices that provide radiation therapy affecting access to care, quality of care, patient satisfaction, disparities, costs or population health in your community? Are they affecting your organization or your organization's members? If so, how?*

   There are two such facilities in this region. Both have been in existence for nearly 30 years and pre-existed many other radiation therapy services. One, in a rural part of our region, provided geographic access in an area served by no other oncology service for many years, and provided transportation and financial access to such services. The other, urban based, is held in local esteem for its patient-centeredness; it provides financial access to care for all to the limits of its own finances.

Of concern, DOH approved a competing hospital-based rad therapy center to the above rural center, despite lack of community need, because they do not recognize centers that are not established. Both the existing and the new center continue to struggle because of lack of recognition of the reality of the physician-owned center.

7. *Current statutes and regulations require certificate of need (CON) approval of certain health care facility projects, equipment acquisitions and service changes. In addition, health care facilities must be licensed and are subject to various regulations governing their operations and physical plant. Physician practices are not generally subject to these regulations. However, Department of Health regulations at 10 NYCRR §600.8 set forth criteria that define the operation of a diagnostic and treatment center and trigger the applicable CON and licensing requirements, whether or not a health care provider is organized as a physician practice.*

    - *Should New York State expand or modify the criteria that define a diagnostic and treatment center under 10 NYCRR §600.8? If so, how?*
    - *How would extending these regulations to certain services or equipment operated by physician practices affect your community? Your organization or its members?*
    - *How would your community be affected if CON and/or licensing requirements were eliminated for certain facility-based services or equipment? Your organization or its members? Please specify the services or equipment you are referencing.*
    - *Some states require a CON for radiation therapy equipment regardless of setting. Should New York State follow suit?*
    - *Some states require CON for advanced imaging equipment (CT scanners, MRIs, PET scanners) regardless of setting. Should New York State follow suit?*
    - *Some states require a CON and/or health facility license for ambulatory surgery, regardless of setting – particularly if an office-based surgery practice has more than one operating room. Should New York State follow suit?*
    - *Some states do not impose CON requirements for the types of equipment or services mentioned above, regardless of setting. Should New York State follow suit?*

At noted at the outset, in general FLHSA is in favor of review of radiation therapy, advanced imaging services and other "high tech" services regardless of auspice. We would also see that principle applied to ambulatory surgery, but have not developed any local information on which to make a recommendation concerning office-based surgery.

8. *New York's Education Law prohibits the practice of medicine by anyone other than a licensed professional or an organization authorized by law. An individual licensed practitioner, professional partnership, professional corporation, professional limited liability partnership, and profession limited liability company are all authorized to practice medicine. Business corporations, not-for-profit corporations and other non-professional organizations are generally prohibited from providing health care, unless they are licensed as a facility or agency under the Public Health law.*

- *Are enhanced physician practices (e.g., "mega" practices, captive professional organizations and faculty practice plans) consistent with the spirit of this prohibition? Please explain your response.*
- *Are they affecting access, quality, disparities, costs and population health in your community?*
- *Are they affecting your organization or your organization's members?*
- *Should New York modify its regulatory approach to the corporate practice of medicine?*

In our area, the largest enhanced physician practices are faculty practice plans. Those groups are fairly clearly consistent with the spirit of the present prohibition against non-professional organizations, and they have contributed to all measures of access, quality, cost control and population health promotion. But they largely, in this region, have not sought to develop freestanding facilities in competition with other practices and facilities. Integrated services generally are a good thing. However, if it looks like a D&T, it should be regulated like a D&T to prevent issues like decreased access or negative impact on essential service providers.

9. *A spectrum of non-hospital urgent and emergent care is evolving in New York. It includes retail clinics, physician-based urgent care, urgent care centers, free-standing emergency departments, and hospital-based emergency departments.*

    - *Are urgent care providers, or lack thereof, affecting quality, access, costs, disparities, patient satisfaction, or population health in your community?*
    - *Are urgent care providers affecting your organization or its members?*
    - *Should New York State modify its approach to regulating these providers? If so, how?*

See our response to Question 3.

FLHSA generally is supportive of free-standing EDs, provided they are hospital sponsored.

10. *In the Rochester area, the Community Technology Assessment Advisory Board provides evidence-based appraisals of the need for new technology and specialized services in both health care facility and physician practice settings and makes recommendations to payers that may have reimbursement implications for providers. Please comment on the effectiveness or value of this type of process and whether such a process would be appropriate for your region.*

FLHSA is, of course, supportive of the CTAAB process. Our local payers are likewise supportive, and are considering an expansion of the CTAAB portfolio to include new technologies, expensive medications and implantable devices. Our local business community is also supportive, and has reacted strongly against a local provider that installed capacity contrary to a CTAAB recommendation.

There are areas of the state which have expressed intense interest in the CTAAB process. While we believe its advisory nature largely shelters it from anti-trust issues, nonetheless its prospects in other areas would be enhanced if it had some anti-trust cover via state recognition.

Thank you for the opportunity to comment on these important matters. We hope the perspectives provided are helpful.

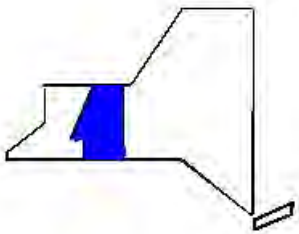
Sincerely

Tom Mahoney, MD
Associate Executive Director

Arthur Streeter
Senior Planner
Director of Review

Attachment

Capacity and Use of High Tech Medical Services in Upstate New York



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June 2005

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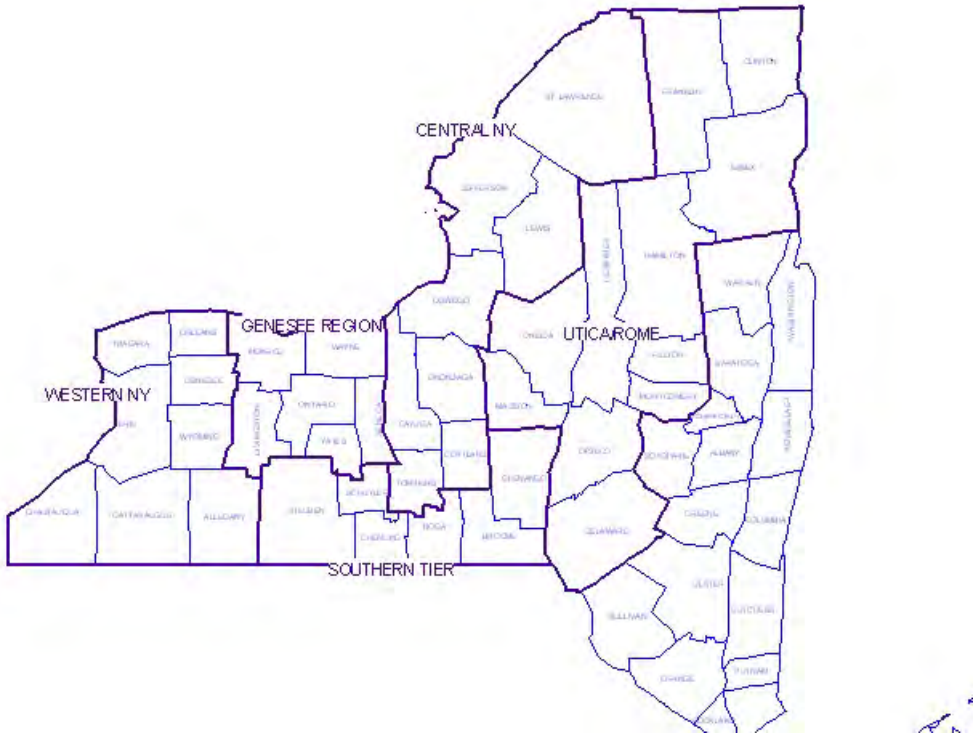
Introduction

In 2004, Excellus BlueCross BlueShield contracted with Finger Lakes Health Systems Agency to compile an inventory of a number of high-tech health care services in multi-county service areas in Upstate New York. This report discusses some of the findings of those inventories. There is substantial evidence in these pages, and elsewhere in the country, that excess capacity leads to increased use of health care services, increased costs, and under-utilized facilities. As will be seen, the relationship is not perfect; there often are intervening factors which affect the relationship of capacity and utilization. Additionally, while not discussed here, the medical literature indicates that excessive capacity and utilization may jeopardize quality of care, lead to heightened competition and loss of cooperation among providers, loss of medical management to non-physician reviewers, and loss of community control of the local health care system.[1]

- Services inventoried include Cardiac Catheterization Labs, CT Scanners, Lithotripters, Megavoltage Radiation Therapy Units, MRI Scanners, PET Scanners, and Surgical Centers.

- Multi-county areas are shown in the map. Defined areas are labeled Western New York, Genesee, Central New York, Southern Tier, and Utica-Rome.

- With the exception of surgery, the calculated use rates are not adjusted for patient migration. This may be a particular problem for the Southern Tier, which data suggest has a net in-migration from Pennsylvania residents.



[1]See the companion paper, *Capacity Matters*, for more discussion of these consequences.

The pages which follow indicate that, often, having more service capacity leads to using more medical care services. Medical care is both science and art – it is hard to say that increased use is un-warranted – but many would say that some of these examples from Upstate NY indicate excessive capacity and excessive utilization. How should the community respond to these potential excesses, which clearly have cost implications?

One school of thought suggests that market economic forces will lead to a "right-sizing" of the health care system. Classic economic theory includes a set of assumptions about free/open/healthy markets that supports this philosophy. Health care systems, however, do not necessarily fit these assumptions. Some of these assumptions include:

- Consumers are informed purchasers.
- The consumers are price conscious.
- Consumers have many choices of service providers.
- There is ease of entry for providers into the market.
- Providers may set prices to meet demand.
- Goods provide benefit only to the individual buying/utilizing them.

Consideration of the list above suggests a lack of fit between health care and classic markets. If it is agreed that health care does not conform to a number of the assumptions of market-oriented economic theory, then questions must be raised about whether "the market" can be expected to provide the needed influences to eliminate any excess capacity. Further, the impact of the market place may adversely affect the delivery system and may not promote community values such as access to care. It is important, then, to provide "extra-market" forces – capacity management – to assure that there is a balance between the public's need for health care services and the supply to meet those needs.

Some technical notes:

- Each graph concerning capacity has supply expressed as **units per million population**, and utilization graphs are expressed as **procedures or cases per 1,000 population**.

- FLHSA believes it has inventoried 100% of each service in the defined areas. Data sources include NYS Department of Health licensure lists, area Yellow Pages, billing lists provided by Excellus, and inquiries to respondents during the surveys. All final inventory/capacity data comes from telephone surveys of the providers.

- FLHSA was not able, however, to get 100% response to requests for utilization data. For some services (CT, PET, MRI, lithotripter, cath lab), response rates near or above 90% were achieved. For other services (surgery, radiation therapy), response rates were lower (55% and 57%, respectively). When possible, missing data was estimated using relationships to known data (for instance, inpatient surgery [known for hospitals] to total surgery).

- With the exception of the data on surgical capacity/use, the enclosed graphs do not attempt to correct for patient migration. Migration, if present, would modify the capacity or use rate per population. For instance, if patients from Area 2 came into Area 1 facilities for services (out-migrated from Area 2, in-migrated to Area 1), the rates calculated for Area 2, absent adjustment for migration, would be too low (a fixed amount of capacity or utilization divided by a service population which is larger than actual), while that for Area 1 would be too high (a fixed amount of capacity or use divided by a service population which is smaller than actual). Migration adjustment was not attempted due to lack of data, but is believed to be negligible because:

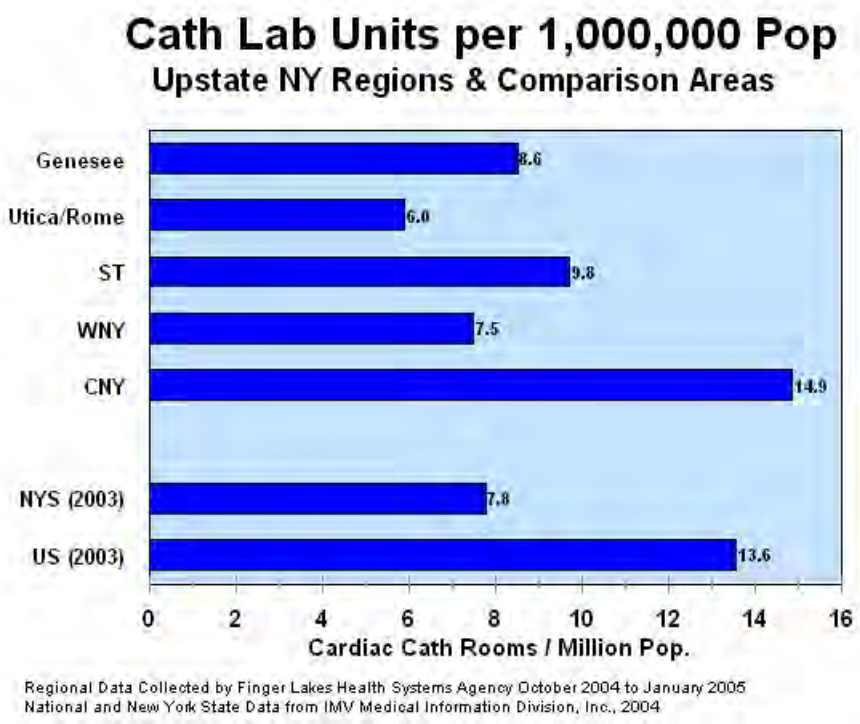
    - The areas being studied are fairly large geographically;
    - Patients tend to travel less for outpatient services, which most of these services are, than for inpatient services;
    - Available data on inpatient services document relatively little migration among the studied areas. There is some in-migration from rural to urban centers, some from the Utica-Rome and Southern Tier areas to Central New York, and, historically, some net in-migration from northern Pennsylvania to the Southern Tier.

Cardiac Catheterization Labs

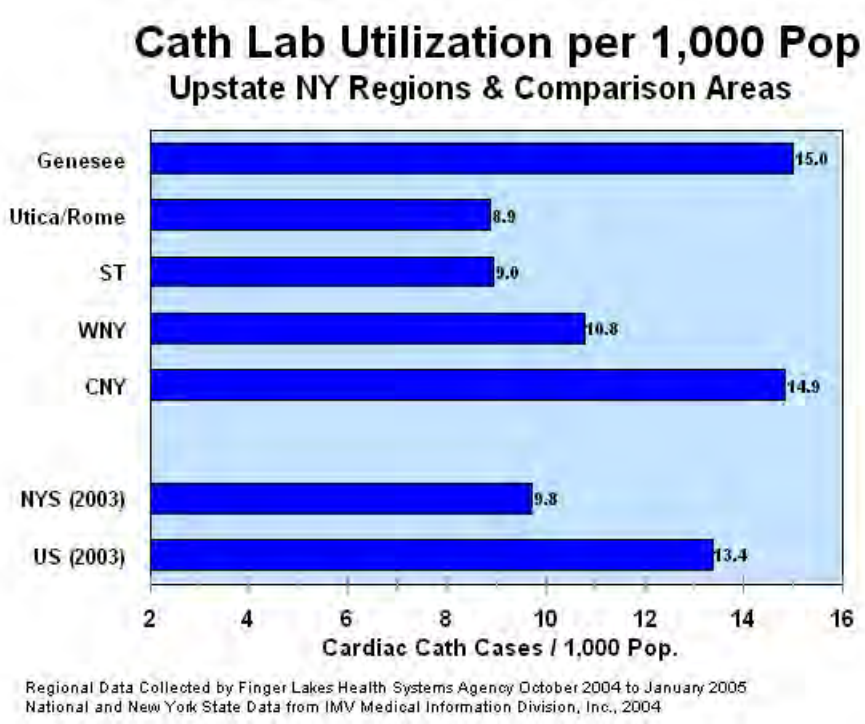
The numbers of cardiac catheterizations – both diagnostic and interventional – are increasing. The graphs below include diagnostics caths as well as angioplasties and electrophysiology studies.

Why does Genesee region have such a high use rate? Does the Genesee rate reflect differences in access to cardiac care? Or, is there a difference in the relative use of surgical vs. medical care in treatment of cardiac diseases?

Our studies find that nearly 80% of cardiac cath labs in Upstate New York have 24-hour staffing, which is important as the cardiac literature increasingly is showing that primary angioplasty is more effective than thrombolytic therapy in cardiac salvage following heart attack.

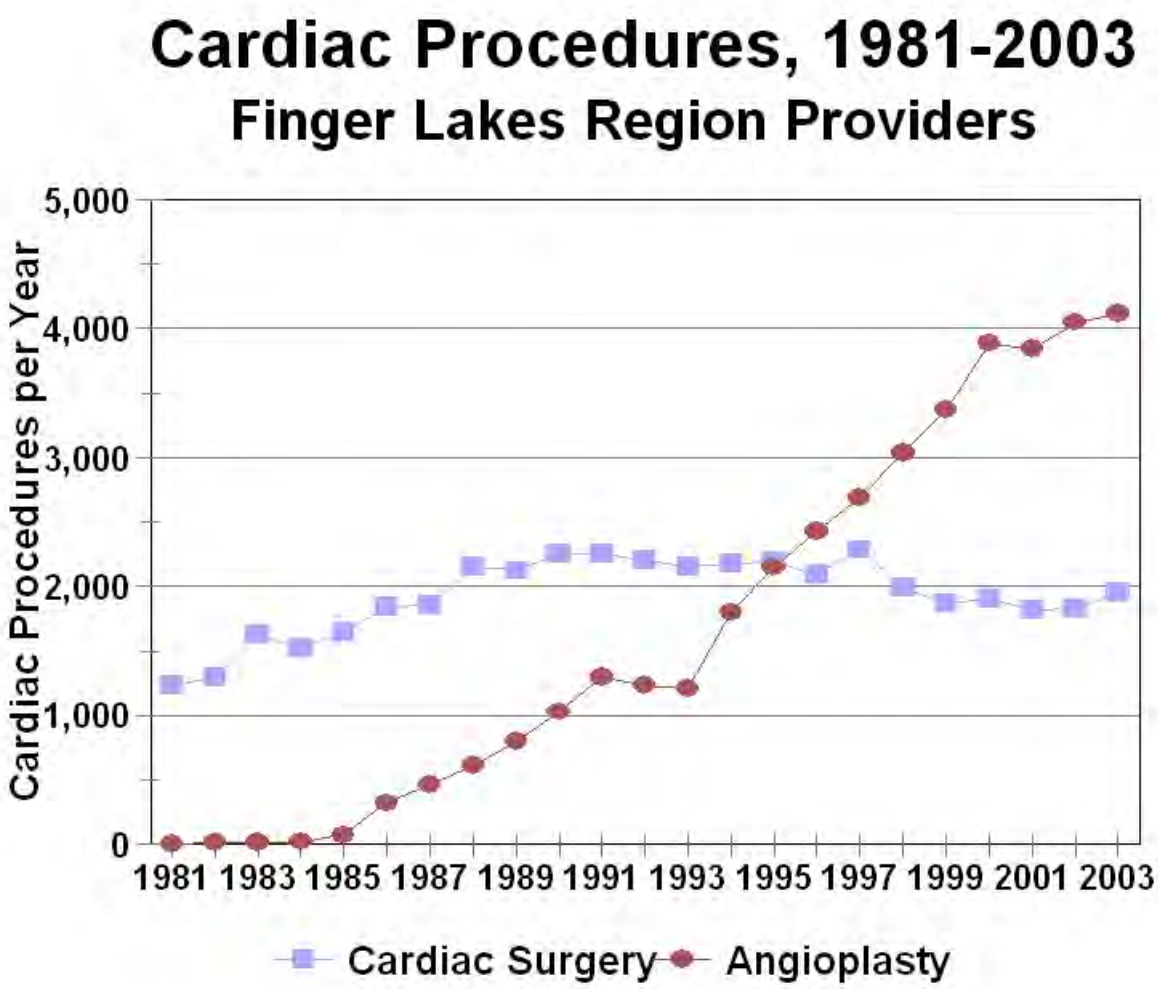


Regional Data Collected by Finger Lakes Health Systems Agency October 2004 to January 2005
National and New York State Data from IMV Medical Information Division, Inc., 2004



Regional Data Collected by Finger Lakes Health Systems Agency October 2004 to January 2005
National and New York State Data from IMV Medical Information Division, Inc., 2004

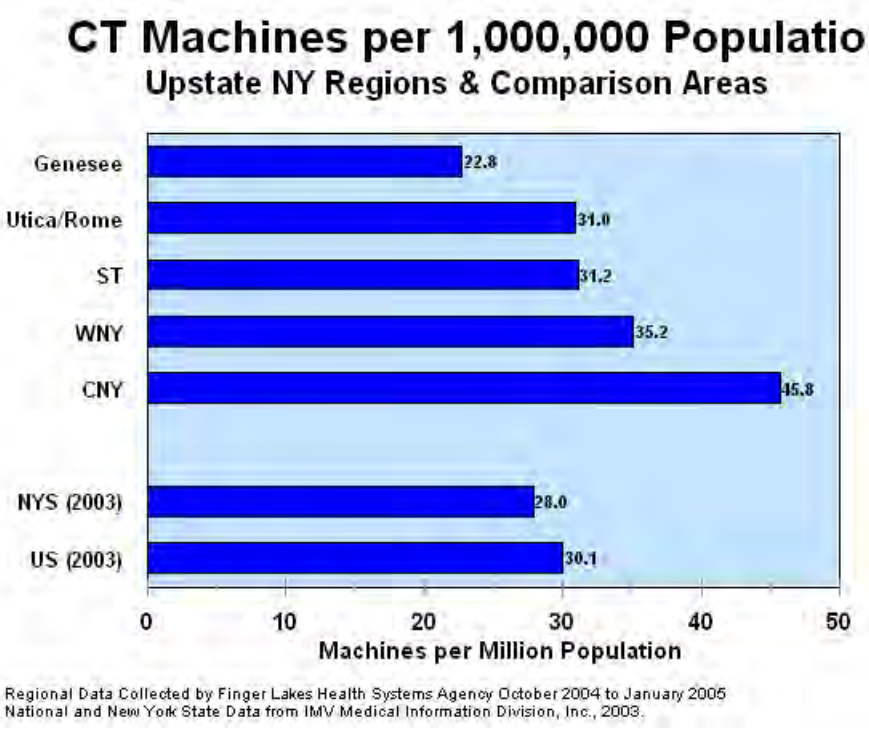
Cardiac catheterization volume is likely to continue to increase due to growth in diagnostic, therapeutic, and electrophysiology catheterization procedures. For instance, the following graph, while specific to one region, demonstrates that angioplasty volume is growing, including some substitution of angioplasty for open-heart surgery.



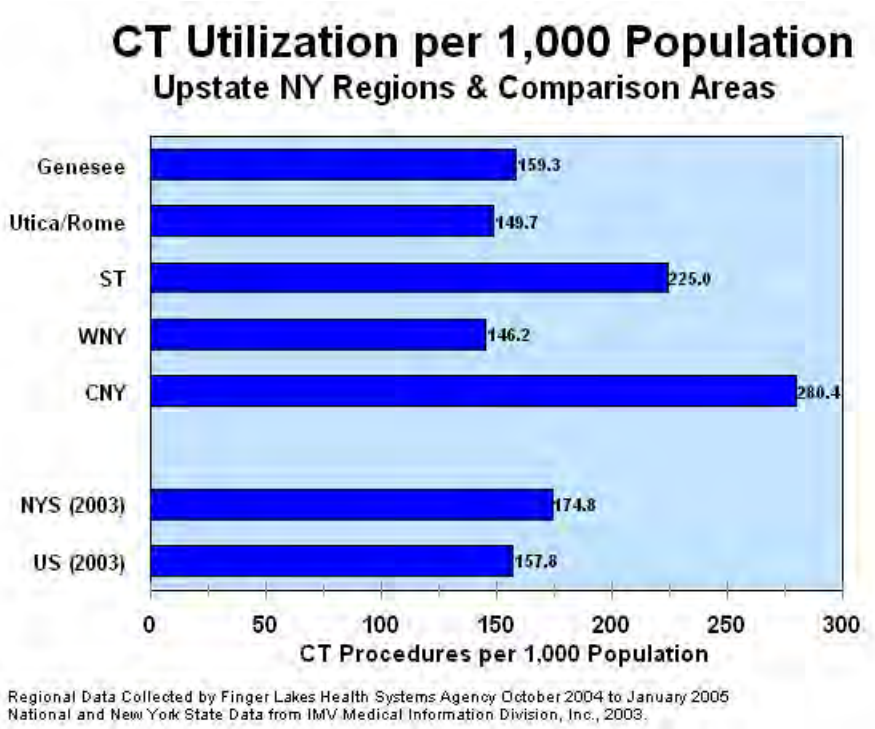
CT Scanners

Computed Tomography (CT) scanning is used to image the body's interior structures, and is present in all hospitals, most radiologic imaging centers, and many physician's offices. It is likely to continue to expand in use due to continuing advances in technology.

Consideration of the utilization slide shows that, averaged across the whole population, 1 person in 6 will get a CT scan each year in WNY, Genesee, and Utica-Rome regions, while approximately 1 in 4 will be scanned in the Southern Tier and CNY regions.



Regional Data Collected by Finger Lakes Health Systems Agency October 2004 to January 2005
National and New York State Data from IMV Medical Information Division, Inc., 2003.



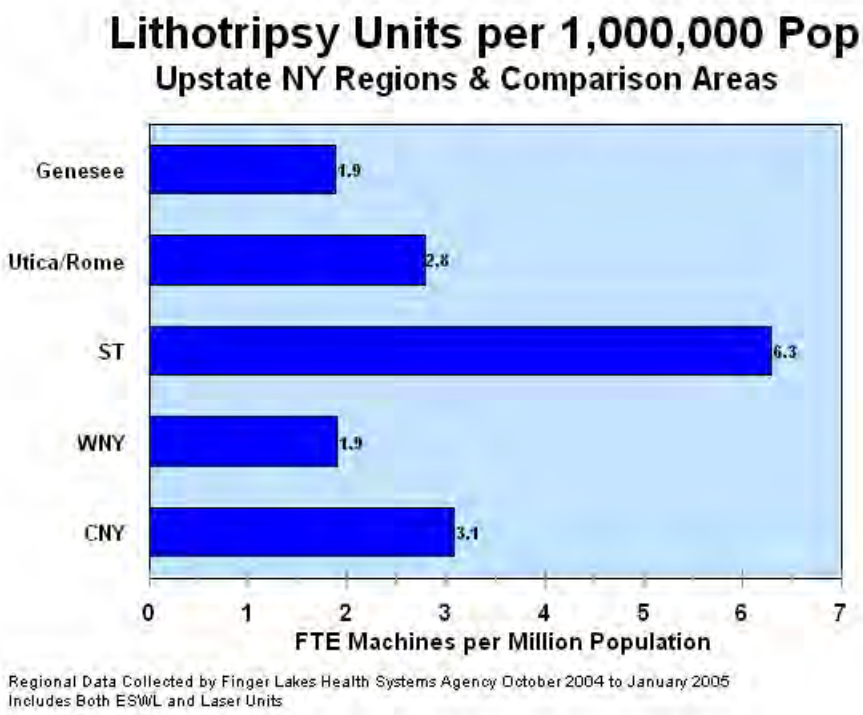
Regional Data Collected by Finger Lakes Health Systems Agency October 2004 to January 2005
National and New York State Data from IMV Medical Information Division, Inc., 2003.

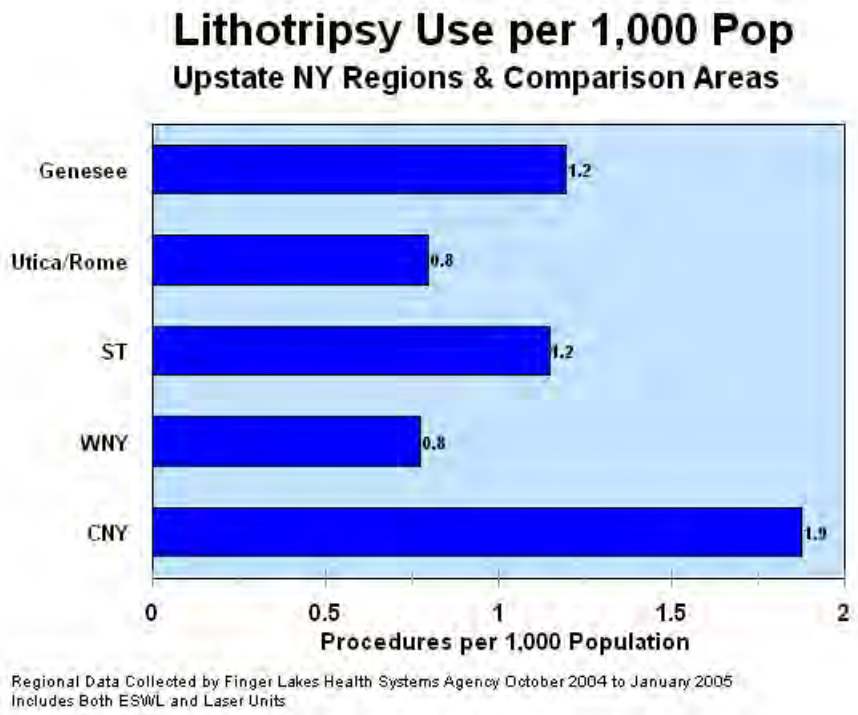
Regional data includes estimated utilization data for 15 of 143 sites (10.4% of sites)

Lithotripters

Lithotripters are used to break kidney stones into pieces small enough to be naturally passed through the system. The following charts include information on both shock-wave technology (ESWL) which in New York mostly has been limited to regional centers, and newer laser technology which is substantially less expensive and more accessible to smaller institutions.

It is unlikely that there are substantial differences in incidence of kidney stones among the populations of the regions. How then to explain the 2X difference in use rates? Migration may be a part, but likely a small part.

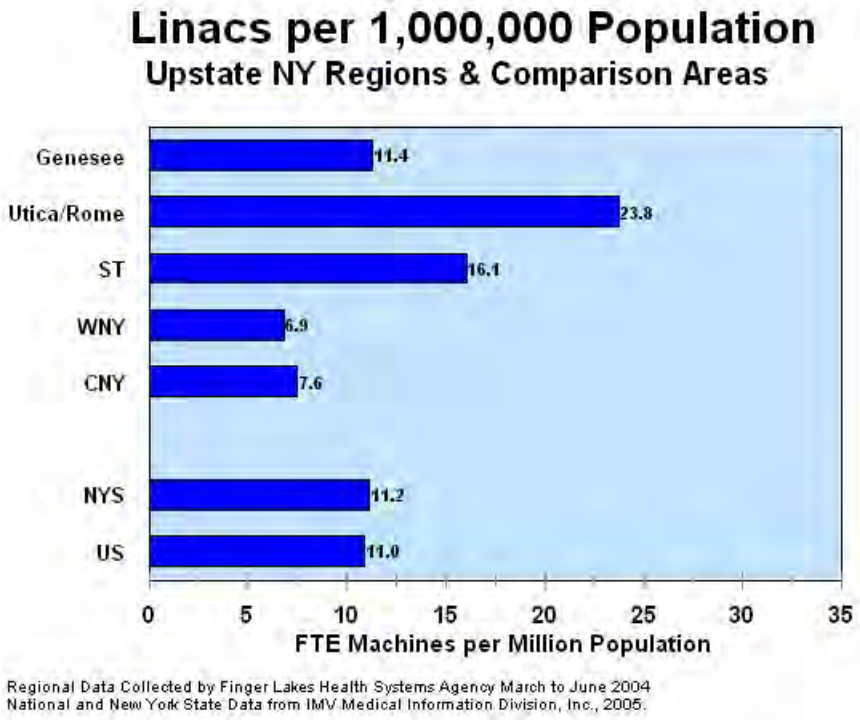


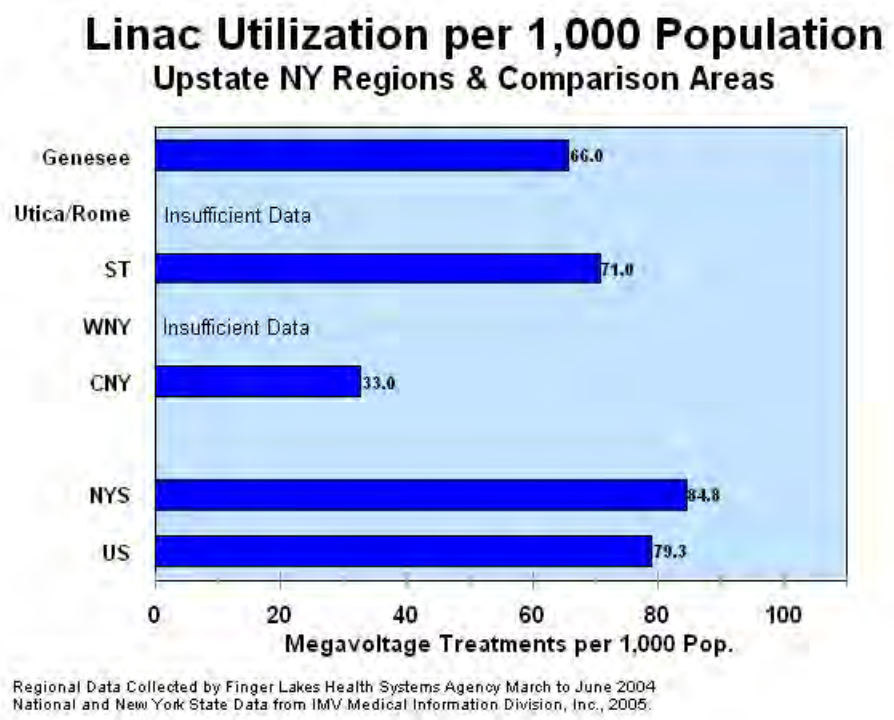


Megavoltage Radiation Therapy Units

Linear Accelerators and other megavoltage units are used for radiation therapy. In its surveys, FLHSA was able to obtain information from many providers on the types of equipment they had available, but nearly half of providers were unwilling to provide utilization data. In two regions (WNY and Utica-Rome), **all** providers declined to provide utilization information. In Western New York, for instance, a major radiation oncology physician group provides services in most installations, and declined to participate. Also declining was Roswell Park Medical Center.

Due to the low participation rate, we are not able to provide some information about linear accelerators.



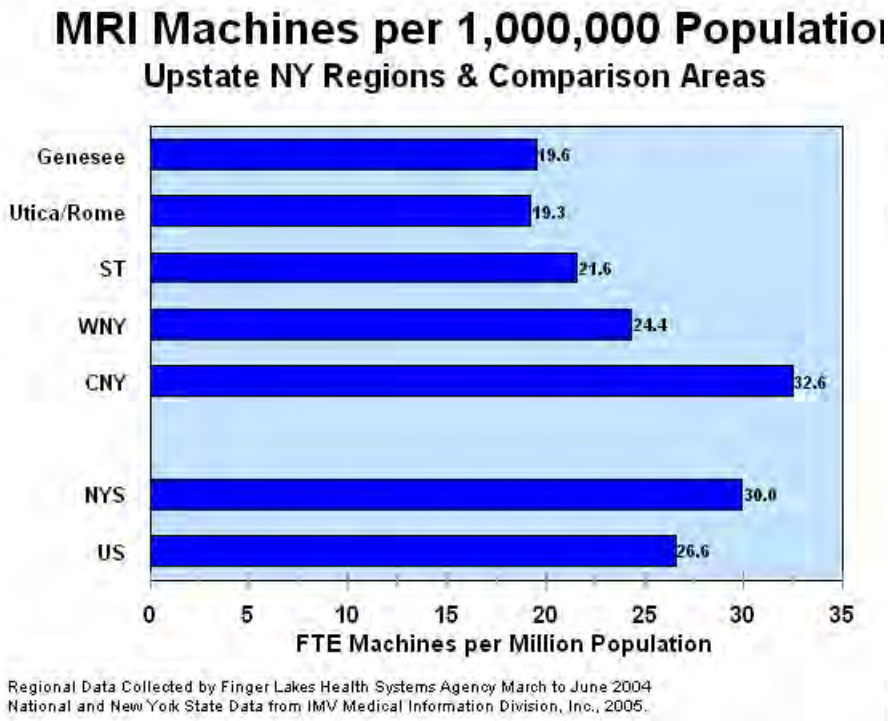


MRI Scanners

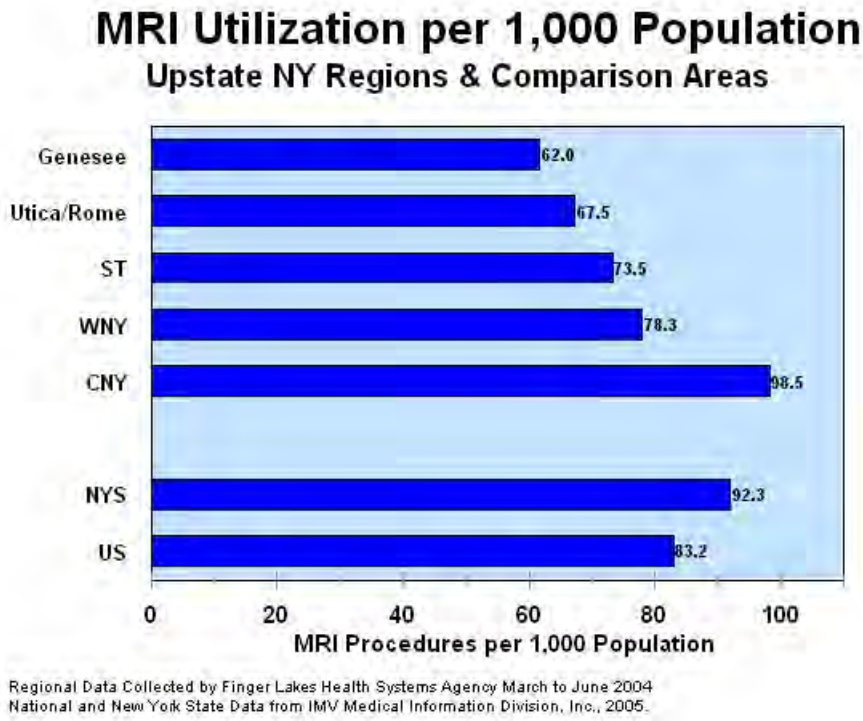
Magnetic Resonance Imaging (MRI) is attractive as a modality because, among other factors, it is good at imaging soft tissues (x-rays, such as in CT scans, are less able to discern differences in density of soft tissues). Also, it is considered safe because it does not use any ionizing radiation (such as using in CT scans (x-rays) or in nuclear medicine, including PET scans). MRIs are produced using a strong magnetic field and radio waves.

This pair of graphs strongly demonstrates the relationship of supply/capacity to utilization. There is no reason to assume that populations living in CNY are sicker than those in Utica-Rome, or those in Genesee region are sicker than those in WNY, yet those in CNY use nearly 50% more than those in Utica-Rome, and those in WNY use more than 25% more scans than populations in Genesee region.

The U.S. has a larger supply of MRIs than most of the studied areas, but New York State as a whole has a larger supply than the U.S. Many MRI units are owned by physicians and are outside of the state's Certificate of Need controls.

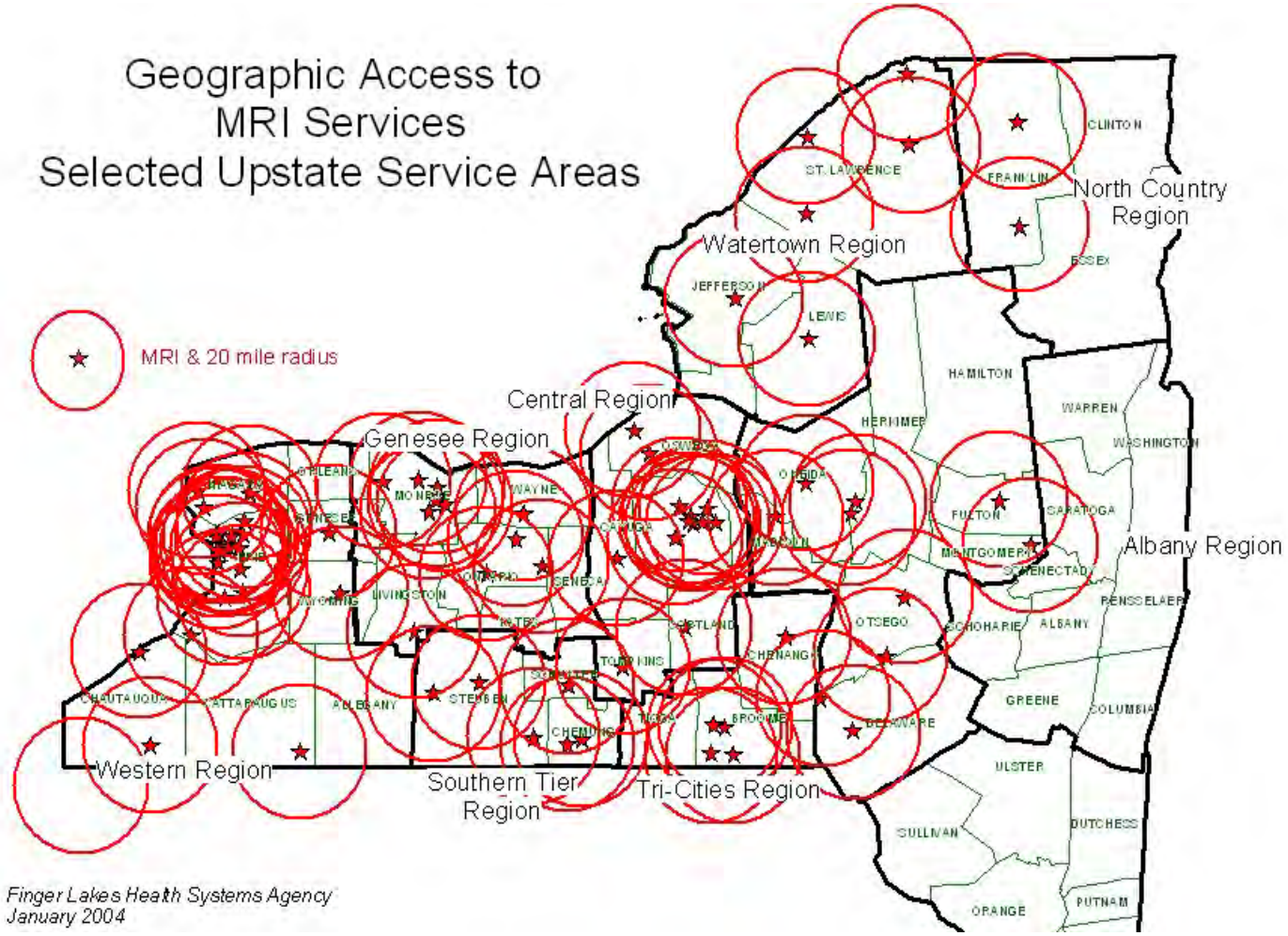


Regional Data Collected by Finger Lakes Health Systems Agency March to June 2004
National and New York State Data from IMV Medical Information Division, Inc., 2005.



Regional Data Collected by Finger Lakes Health Systems Agency March to June 2004
National and New York State Data from IMV Medical Information Division, Inc., 2005.

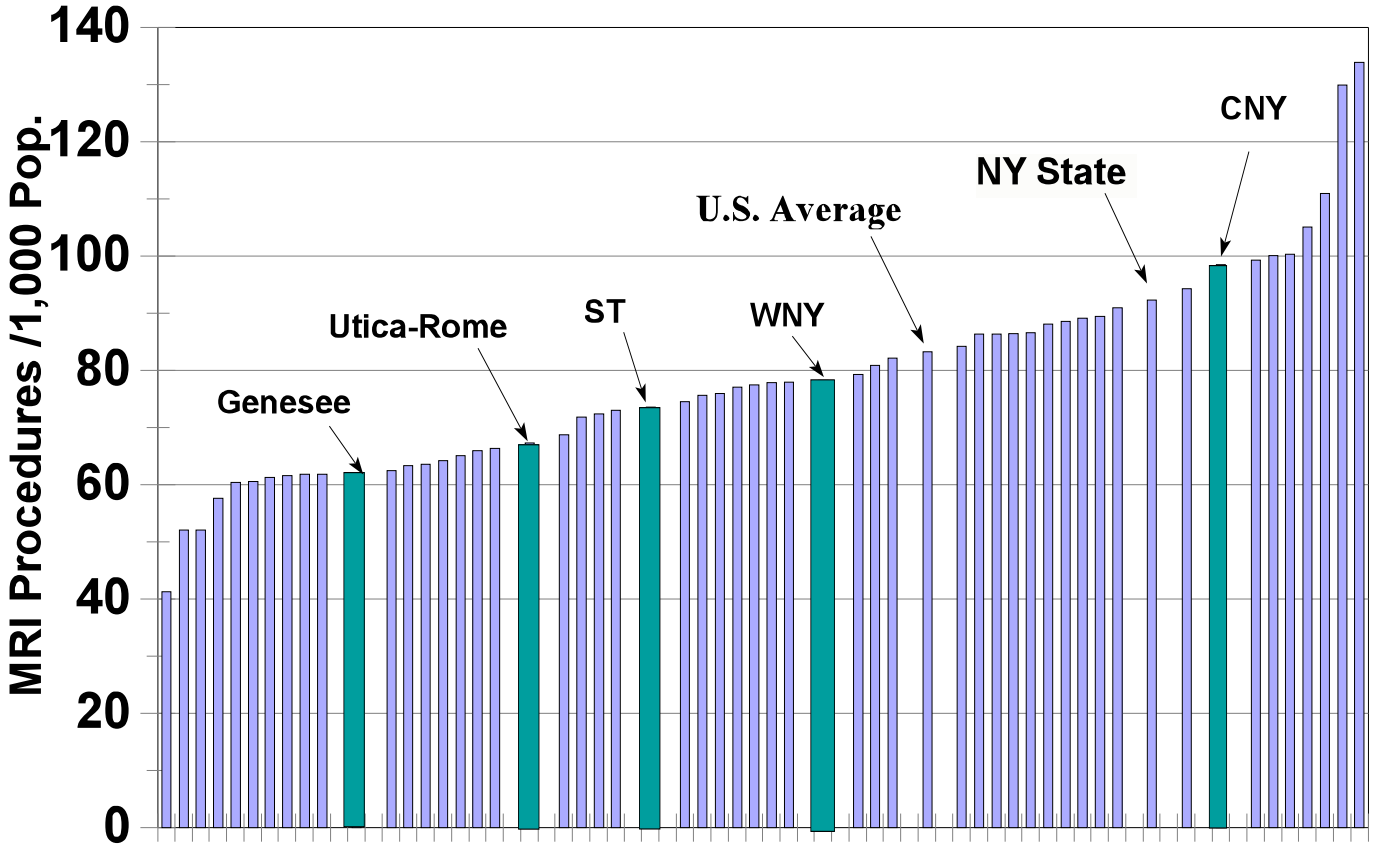
Most areas of Upstate New York have good access to MRI services. The circles on this map represent approximately 30 minutes travel time. With the exception of a few areas in the western Southern Tier and in the Adirondacks, MRI service is available. Note that many of the services in more rural areas are mobile and not available daily; however, about 90% of MRI scans are performed on an ambulatory basis, so daily availability is not as critical as it would be for an inpatient service.



If the Upstate areas were states, they would range from near the bottom 10 states to among the top 10 states in MRI use rate.

2004 MRI Utilization

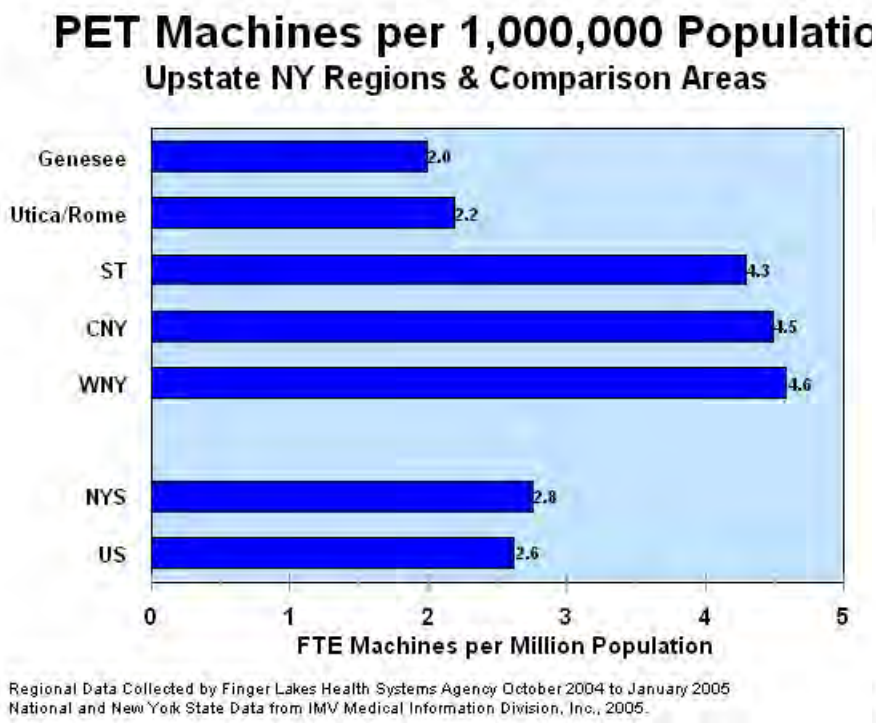
Upstate New York Areas and U.S. States

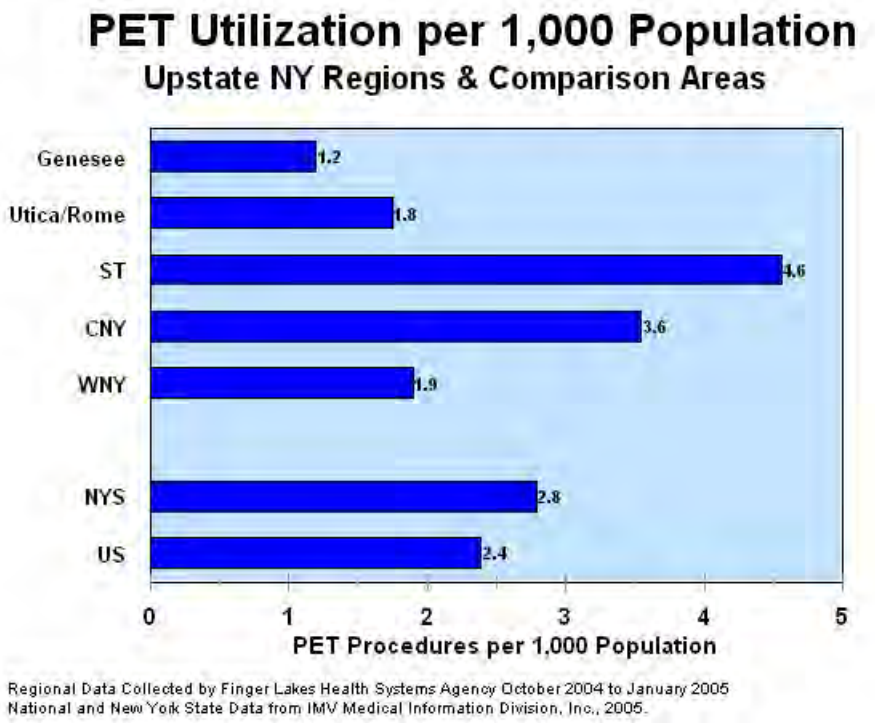


Data Sources: FLHSA 2004 Survey
IMV 2004 MRI Benchmark Report

PET Scanners

PET scanning differs from other modalities in imaging metabolic processes more than body structures. A fairly recent development, fusing CT and PET scan images, improves the spacial localization of the PET images. At this point in its development, utilization is controlled more by demand management (such as prior authorization requirements by insurers) rather than availability/capacity. Clinical indications are expanding. Most demand is currently tied to oncology (cancer), and the effect of PET on treatment outcomes is still being determined.

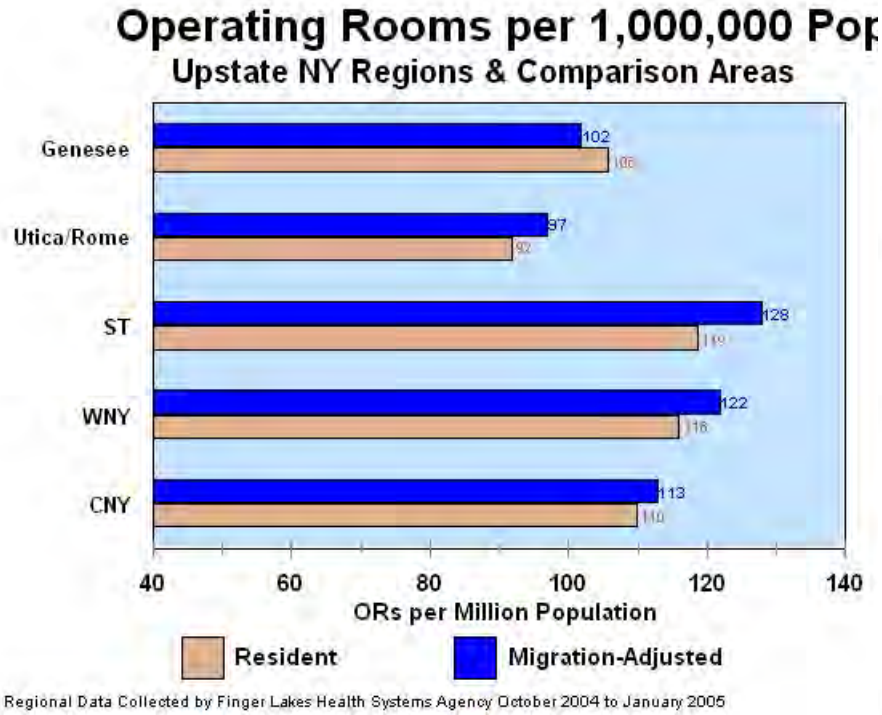


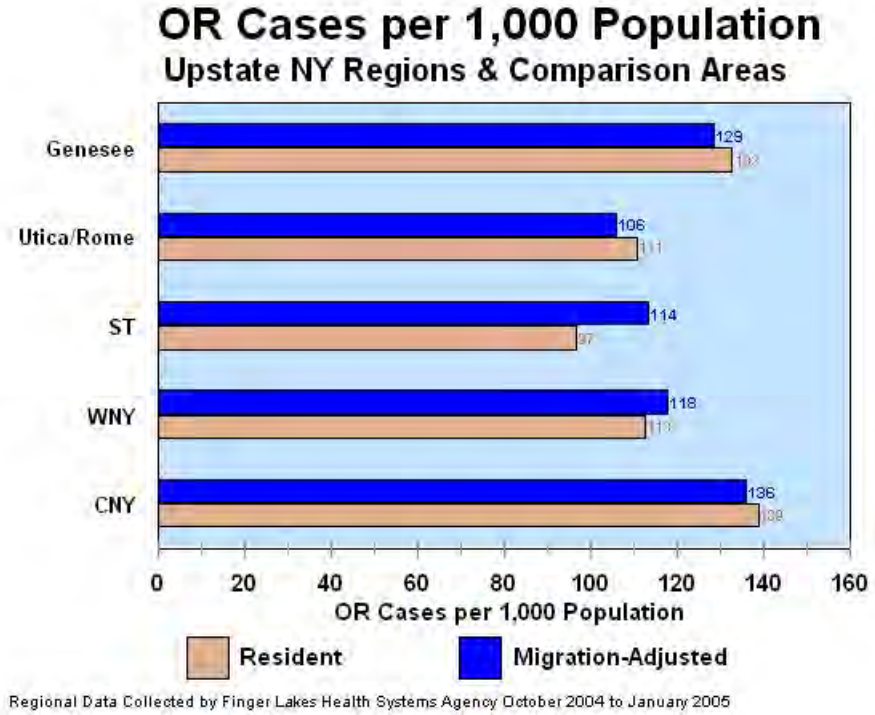


Surgical Centers

The following graphs include surgery in both inpatient and ambulatory settings, but excludes endoscopic procedures. The graphs depict both resident and migration-adjusted rates; the migration adjustment using inpatient migration patterns, although about 75% of surgery is now performed on an ambulatory basis.

While FLHSA was able to obtain data on the number and type of operating rooms from all providers, it could only elicit data on utilization for approximately 55% of providers. We have found there is a good correlation for urban vs. rural and larger vs. smaller hospitals between inpatient surgeries (for which there is data available) and total surgical cases, and have used those relationships to estimate missing data.





Includes estimated utilization data when data is unknown. Migration adjustment does not include in and out-migration from Pennsylvania

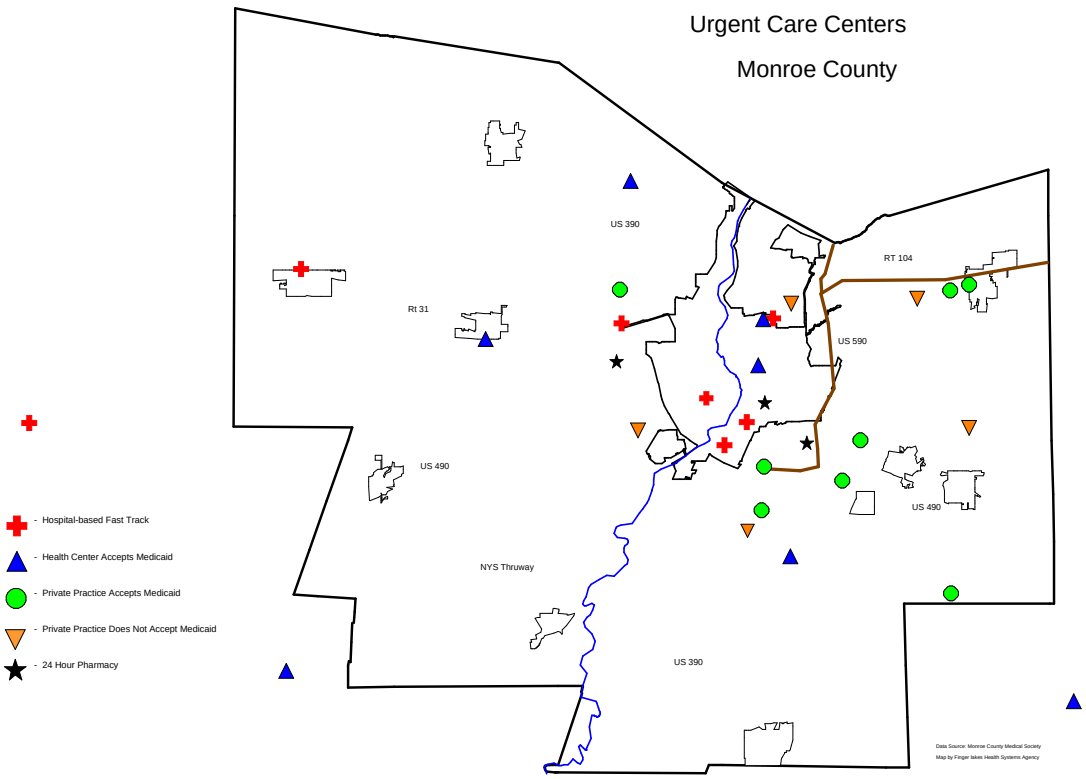
Resident = Local capacity divided by local population

Adjusted = Local capacity divided by migration-adjusted population
(Surgical inpatient migration used for migration adjustment)

Finger Lakes Health Systems Agency (FLHSA) is a health planning organization whose mission is to promote the delivery of accessible, affordable health care services to the population of the region. From its origins in the 1950s, health planning has been an integral part of this community's health care system and has been supported by community leaders, health care providers, insurers, and county governments.

As health care in the region becomes increasingly competitive, FLHSA assesses the effects of that change on the community. It does this by:

- tracking shifts in access to health services and insurance
- monitoring changes in health status of the population
- assessing health needs in the community
- providing community-wide health data.


Urgent Care Centers
Monroe County
US 390
RT 104
Rt 31
US 590
US 490
US 490
NYS Thruway
US 390
- Hospital-based Fast Track
- Health Center Accepts Medicaid
- Private Practice Accepts Medicaid
- Private Practice Does Not Accept Medicaid
- 24 Hour Pharmacy
Data Source: Monroe County Medical Society
Map by Finger lakes Health Systems Agency

FINGER LAKES REGION
MRI CAPACITY AND UTILIZATION REPORT

Data from January 2011 – December 2011

Prepared January 2013

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Contents

Section One: Summary

The Finger Lakes Health Systems Agency (FLHSA) undertook a survey[1] of the Finger Lakes region's MRI services in 2012 in order to inventory the services available in the region, to monitor the effect of additions of capacity made in recent years, and to track the pace of MRI utilization. The majority of the information included in this report comes from responses from providers during the 2012 survey, and includes utilization data for calendar year 2011 and inventory data as of December 31st, 2011. To allow for consistent analysis, however, data from earlier surveys or estimates was used for the few non-responding facilities.

Number of Machines

Presently there are 26 MRI service sites in the 9-county Finger Lakes region, with the equivalent of 35.8 full-time machines. All hospital sites in the region except two subsidiary campuses have on-site MRI availability. One freestanding site was closed in 2011.

Utilization

Based on the survey responses, MRI utilization increased by 3.8% in 2011 compared to 2010. This compares to the 1.5% increase in utilization between 2009 and 2010, and follows the general trend of slow growth since 2004.

As shown in tables 8 through 11, the region's 35.8 full-time units experienced average utilization of 3103 exams per unit in 2011; this is an increase from last year. There is variation in average utilization rates based on the type of unit used (e.g. mobile, stationary). Hospital-based stationary units completed an average of approximately 4450 exams. An average of 1160 exams were completed on mobile MRI units. Freestanding (but fixed) units completed an average of 3000 exams per unit.

National Comparisons

On a per capita basis, the region uses substantially fewer MRI exams than most of the country. This may reflect both the effect of review of clinical appropriateness and the control of new MRI capacity in this region.

Regional Need

Based on the benchmark chosen[2] and on current utilization—111,092 procedures in 2011—one

[1] Unless otherwise stated, data come from FLHSA surveys from 1996-2012.

[2] In previous analysis for MRI machines needed in this region, a local benchmark of 3,625 MRI studies per machine was established. It was equal to 5.5 workdays per week, 10 hours per day [many facilities in the region are open longer per day than this], 45 minutes per study and 95 percent "occupancy." However, local experience had indicated that MRI units are capable of higher utilization per year; comparisons with 4,000 and 5,000 exams per year are considered.

could postulate a regional demand for 22 to 30 full-time machines at the end of 2011. This compares to the current 35.8 regional machine capacity.

Future Demand

Based on the projections below, the current stock of 35.8 MRI machines will accommodate up to a 10% increase in demand each year over the coming years. At this time, there is no need for additional machines. Table 1 provides projections using a consistent growth rate (e.g. 5%/year) in 2012 and 2013.

Table 1: Number of MRI Machines Needed in Finger Lakes Region at End of 2013

Projected Utilization Increase*	Use Rate Per Machine		
	3625	4000	5000
5 %	33.8	30.6	24.5
7.5%	35.4	32.1	25.7
10 %	37.1	33.6	26.9
12.5%	38.8	35.2	28.1
15 %	40.5	36.7	29.4

* Above the 2011 utilization of 111,092 procedures
Present resource = 35.8 FTE MRI Units

Section Two: Capacity

Table 2 lists the MRI sites in the region. Table 3 describes the manufacturer, magnet type, type of installation and magnet strength for the MRI units of each respondent.

Table 2: Inventory of MRI Machines in the Finger Lakes Region, End of Calendar Year 2011

	Facility	Units	Fixed/ Mobile	CON-Approved	Ownership
Hospital-Stationary	Arnot-Ogden	1.0	F	X	Hospital
	FF Thompson	1.0	F	X	Hospital
	Geneva General	1.0	F	X	Finger Lakes Radiology
	Highland	1.0	F	X	University Imaging
	Unity	1.0	F		Borg & Ide Imaging
	Rochester General	2.3[#]	F	X	Rochester Diagnostic Imaging
	Rochester General	1.0	F	X	Hospital
	St. Joseph's[3]	1.0	F	X	Hospital
	Strong	4.0	F	X	Hospital
Hospital-Mobile	Arnot-Ogden	0.5	M		InSight Health Corp.
	Corning Community	1.0	M	X	Alliance Imaging
	Clifton Springs	1.0	M	X	King's Medical Group
	Ira Davenport	1.0	M	X	King's Medical Group
	Lakeside	1.0	M	X	InSight Health Corp.
	Newark-Wayne	1.0	M		Alliance Imaging
	NH Noyes[4]	1.0	M		Northern Lights Imaging
	St. James Mercy	1.0	M		InSight Health Corp.
	Schuyler	1.0	M	X	King's Medical Co.
Freestanding	Culver Road	1.0	F		Borg & Ide Imaging
	Elizabeth Wende B.C.	1.0	F		E.W.B.C.
	Hagen Drive	1.0	F		Borg & Ide Imaging
	Lac de Ville Blvd	4.0	F		University Medical Imaging
	Lattimore Rd	1.0	F		Borg & Ide Imaging
	Open MRI of Elmira[5]	1.0	F		Open MRI of Elmira
	Ridgeway Ave	1.0	F		Borg & Ide Imaging
	Senator Keating Blvd	2.0	F		Borg & Ide Imaging
	White Spruce Blvd	1.0	F		Borg & Ide Imaging
	Science Park	1.0	F		University Medical Imaging
	TOTAL	35.8	F= 27.3 M= 8.5	13 sites with CON approval	

one unit is used on a limited basis, for selected patients only

[3] 2010 data was used for all entries of St. Josephs
[4] 2009 data was used for all entries of NH Noyes
[5] 2006 data was used for all entries of Open MRI of Elmira.

Table 3: MRI Equipment in the Finger Lakes Region, 2011

Machine Type	Facility	Manufacturer	Magnet Type*	Stationary or Mobile	Power (Tesla)
Hospital-Stationary	Arnot-Ogden	Philips	S	Stationary	1.5
	FF Thompson	Philips	P	Stationary	1.5
	Geneva General	Siemens	S,O	Stationary	1.5
	Highland	GE	S	Stationary	1.5
	Unity	GE	S	Stationary	1.5
	Rochester General	GE	O	Stationary	0.3
	Rochester General	GE	P	Stationary	1.5
	Rochester General	GE	P	Stationary	1.5
	Rochester General	GE	S	Stationary	1.5
	St. Joseph's	Philips	P	Stationary	1.5
	Strong	GE	P	Stationary	1.5
	Strong	Philips	P, O	Stationary	1.0
	Strong	GE	P	Stationary	1.5
	Strong	GE	P	Stationary	1.5
Hospital-Mobile	Arnot-Ogden	Siemens	S	Mobile	1.5
	Corning Community	Siemens	S,O	Mobile	1.5
	Clifton Springs	GE	S	Mobile	1.5
	Ira Davenport	Siemens	S	Mobile	1.5
	Lakeside	GE	S	Mobile	1.5
	Newark-Wayne	GE	S	Mobile	1.5
	NH Noyes	Siemens	P	Mobile	1.0
	St. James Mercy	GE	S	Mobile	1.5
	Schuyler	Philips	S	Mobile	1.5
Freestanding	Culver Road	GE	S	Stationary	1.5
	Elizabeth Wende B.C.	Siemens	S	Stationary	1.5
	Hagen Drive	Siemens	S	Stationary	1.5
	Lac de Ville Blvd	GE	S	Stationary	1.5
	Lac de Ville Blvd	GE	S	Stationary	1.5
	Lac de Ville Blvd	GE	S	Stationary	1.5
	Lac de Ville Blvd	GE	S	Stationary	3.0
	Lattimore Rd	GE	S, O	Stationary	1.2
	Open MRI of Elmira	Hitachi	P, O	Stationary	0.3
	Ridgeway Ave	GE	S	Stationary	1.5
	Senator Keating Blvd	GE	S	Stationary	3.0
	Senator Keating Blvd	GE	S	Stationary	1.5
	White Spruce Blvd	GE	S	Stationary	1.5
	Science Park	GE	S	Stationary	3.0

*S= Superconducting O= Open Architecture P= Permanent

Staffing

Table 4 describes by respondent the total number of hours and days per week the equipment is staffed. With some expansion of capacity and minimal growth in volume, many units are still operating more hours per week than in previous years; in Monroe County, total staffed unit hours increased from 1,375 in 2005; 1,720 in 2010; and 1774.5 in 2011, an average of 74 hours per week per unit. Almost all units are operating more than 8 hours per day and approximately 40% are open on at least some weekend hours. Nationally[6] less than 30% of hospital fixed sites were open over 13 hours per weekday (average 11.0 scheduled hours), and about 47% had no scheduled hours on weekends.

Table 4: MRI Service Staffing

	Facility Name	Days/Week	Hours/Week
Hospital Stationary	Arnot-Ogden	7	97
	FF Thompson	6	69
	Geneva General	5	60
	Highland	6	74
	Unity	7	100.75
	Rochester General	5	70
	Rochester General	7	118
	St. Joseph's	5	50
	Strong	7	168
Hospital – Mobile	Arnot-Ogden	3	30
	Corning Community	5	50
	Clifton Springs	5	45
	Ira Davenport	5	42.5
	Lakeside	5	45
	Newark-Wayne	5	47.5
	NH Noyes	5	42.5
	St. James Mercy	6	45
	Schuyler	5	42.5

[6] IMV 2012 Report

Table 4: MRI Service Staffing (Continued)

	Facility Name	Days/Week	Hours/Week
Freestanding	Culver Road	5	51.25
	Elizabeth Wende B.C.	5	48.75
	Hagen Drive	5	42.5
	Lac de Ville Blvd	7	96.5
	Lattimore Rd	6	52.75
	Open MRI of Elmira	5	60
	Ridgeway Ave	5	51.25
	Senator Keating Blvd	6	55.25
	White Spruce Blvd	5	42.5
	Science Park	7	77

A measure of whether there is sufficient capacity to provide a medical care service is how long a potential patient must wait to obtain the service. The current survey (Feb. 2012) provides information on wait time, both for urgent and routine service. Previous surveys expressed variability of waiting times, sometimes indicating an extended wait for service and at other times little or no wait. The current survey indicates there is a relatively short wait time for service, suggesting a relatively robust capacity compared to demand.

Table 5: Average Waiting Time to Schedule an MRI exam

	Facility Name	Emergent Cases (Days)	Non-emergent cases (Days)
Hospital - Stationary	Arnot-Ogden	0	1.5
	FF Thompson	0	2.5
	Geneva General	0	1.5
	Highland	0	1.5
	Unity	0	0
	Rochester General	0	1.5
	Rochester General	0	5
	St. Joseph's	0	0
	Strong	0	2.5
Hospital - Mobile	Arnot-Ogden	0	3.5
	Corning Community	N/A	N/A
	Clifton Springs	0	2
	Ira Davenport	0	1
	Lakeside	0	1

	Facility Name	Emergent Cases (Days)	Non-emergent cases (Days)
Hospital- Mobile (Continued)	Newark-Wayne	0	1
	NH Noyes	1	2
	St. James Mercy	0	1
	Schuyler	0	0
Freestanding	Culver Road	0	0
	Elizabeth Wende B.C.	1.5	3
	Hagen Drive	0	0
	Lac de Ville Blvd	0	0
	Lac de Ville Blvd - 3.0T MRI only	0	8.5
	Lattimore Rd	0	0
	Open MRI of Elmira	0	0
	Ridgeway Ave	0	0
	Senator Keating Blvd	0	0
	White Spruce Blvd	0	0
	Science Park	2.5	5

Table 6 provides each respondent's estimate of the average number of minutes of machine time a patient spends per exam. Despite increasingly complex technique, exam times have remained stable over time.

Table 6**:** Average Number of Minutes per Exam

	Facility name	Minutes per Exam
Hospital Stationary	Arnot-Ogden	37
	FF Thompson	45
	Geneva General	40*
	Highland	45
	Unity	30-45
	Rochester General	40
	St. Joseph's	31*
	Strong	60
Hospital Mobile	Arnot-Ogden	37
	Corning Community	25
	Clifton Springs	45
	Ira Davenport	40
	Lakeside	45
	Newark-Wayne	40

	Facility name	Minutes per Exam
Hospital- Mobile (continued)	NH Noyes	60*
	St. James Mercy	30-35
	Schuyler	30
Freestanding	Culver Road	30-45
	Elizabeth Wende B.C.	23
	Hagen Drive	30-45
	Lac de Ville Blvd	35
	Lattimore Rd	30-75
	Open MRI of Elmira	30-75*
	Senator Keating Blvd	30-45
	White Spruce Blvd	30-45
	Science Park	90

*Data were provided in surveys from previous years

The information displayed above, when used in conjunction with the staffing information in Table 4, can be used as a baseline for development of capacity estimates for MRI. For example:

Table 7: Potential Capacity Standard per MRI Unit (Based on Local Utilization Patterns in Table 4 and Table 6)

Work Days Per Year	Hours/Day	Minutes/Exam	Exams Per Year*
365	24 Workdays/ 12 Weekends	60	7,400
250	8	45	2,650
285	10	45	3,625

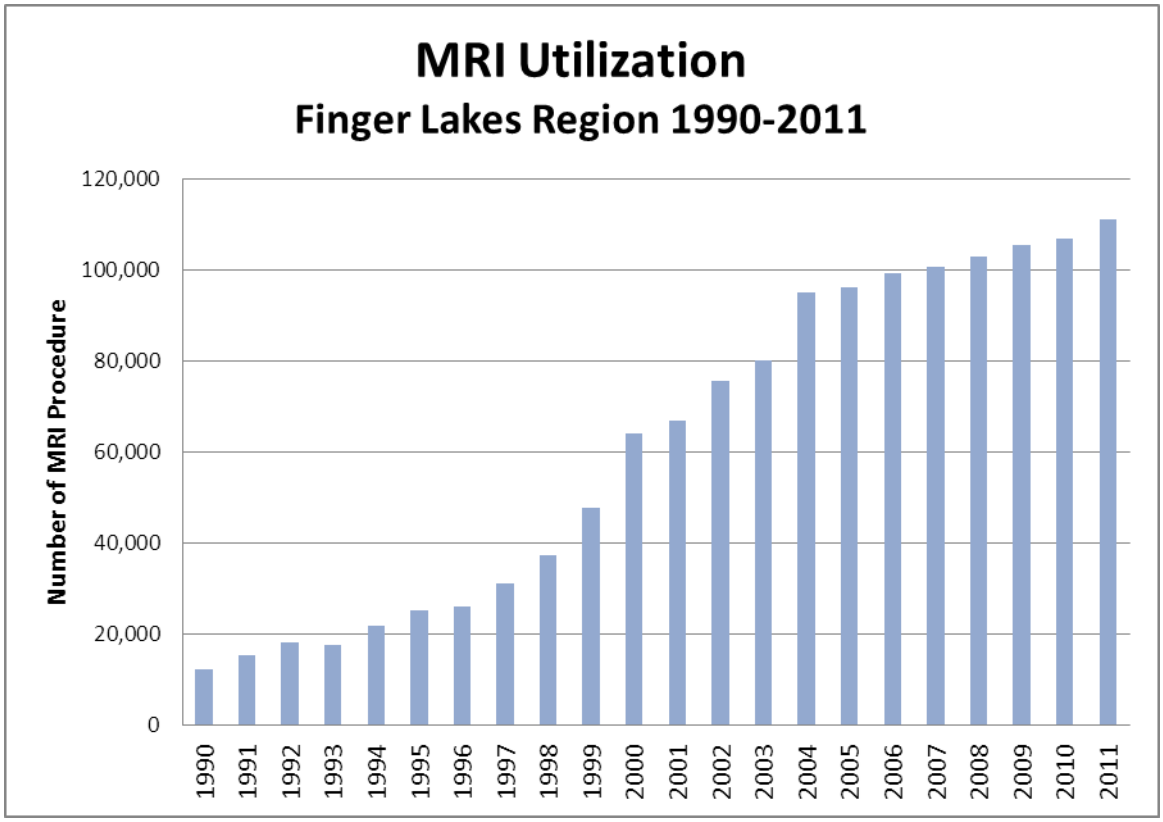
* Includes a 95% "occupancy" factor

Section Three: Utilization

Analysis

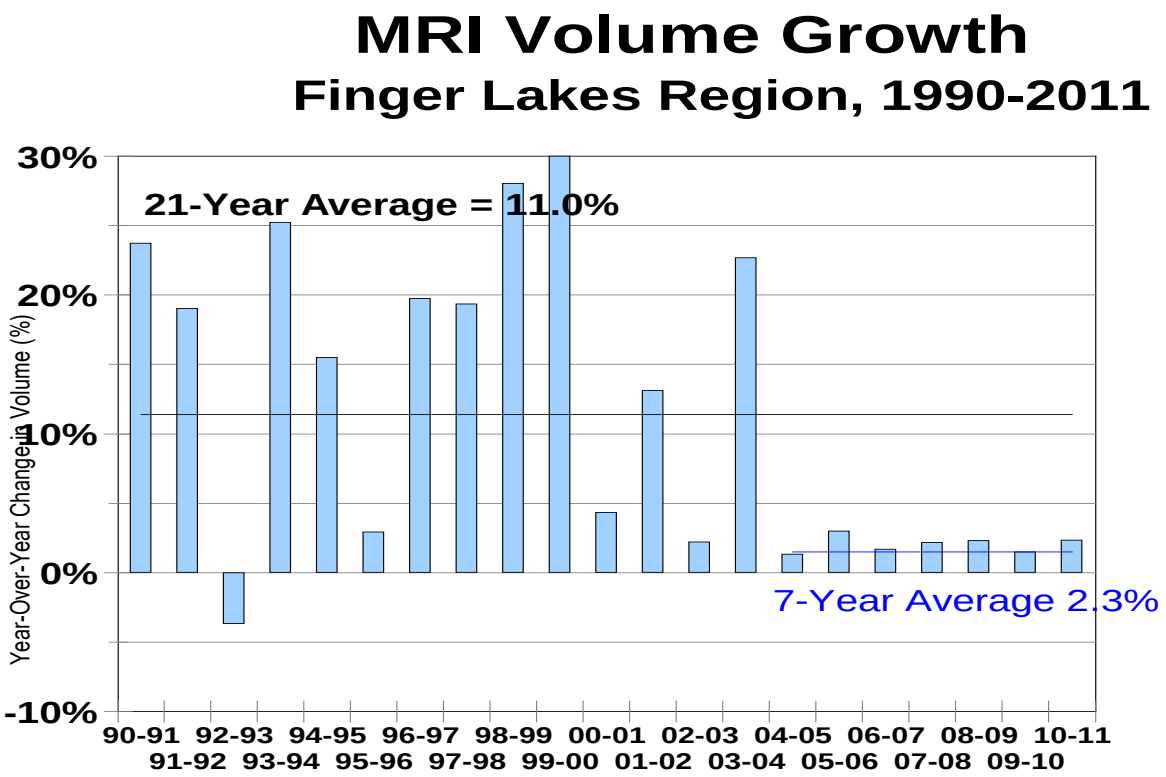
The largest increase in total MRI procedures in the Finger Lakes region occurred between 2003 and 2004 when utilization increased 22.7% (77,407 procedures in 2003 to 94,961 procedures in 2004). Since then, perhaps influenced by more stringent utilization review including health plan pre-authorization, the rate of change has remained relatively flat, increasing only 17.0% between 2004 and 2011 (94, 961 to 111,092 procedures), or 2.3% per year.

Figure 1: MRI Utilization in the Finger Lakes Region



In the 16 years between 1996 and 2011, MRI volume more than tripled, and as shown in the figure below, volume exhibited a compound growth rate of approximately 11.0% from 1990 to 2011. In 2001, clinical and financial restraints were put in place for HMOs in and around Monroe County, sharply reducing the growth of MRI use. Following 2001, there was a concern that growth would return to the long-term average; for the most part, that does not appear to have happened. New utilization management programs were instituted by the local insurers in 2008.

Figure 2: Growth in MRI Utilization in the Finger Lakes Region



Data Source: FLHSA Surveys of MRI Providers

Utilization by Facility Type

The growth of total MRI Volume in the region from 1996 through 2011 by MRI site type is presented in Figure 3. As seen in Tables 8, below, MRI procedures per unit have declined compared to the first half of this decade, coinciding with installation of a number of units in 2007 and expansion of days per mobile unit. Nationally, IMV reports average use per unit of 3,355 for hospital-based units and 3,275 for non-hospital units. As seen in Table 7, use of 3,625 per unit or higher is consistent with local use patterns of hours and time per MRI procedure. These data would suggest that there is no need for additional MRI capacity at this time in the region.

Figure 3: Total MRI Procedure Volume by Site Type

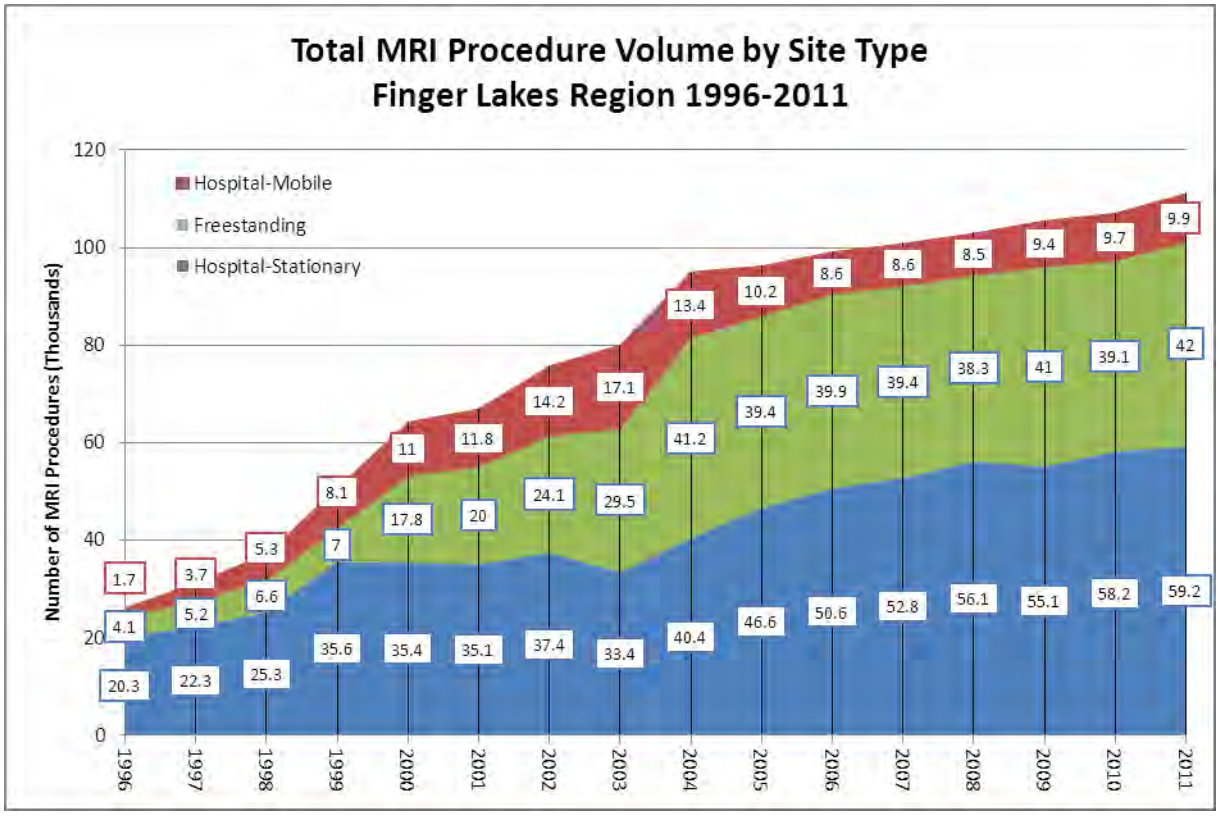


Table 8: Average Number of Exams per MRI (Regional Total)

Year	Total Utilization	# of Units Reporting	Average exams/unit
1996*	26061	9.5	2743
1998	37229	10.1	3686
2000	64156	19.1	3359
2002	75729	22.3	3396
2004	94961	27.8	3416
2006	99114	28.0	3540
2008	102998	34.6	2977
2009	105384	36.7	2871
2010	106975	35.8	2988
2011	111092	35.8	3103

* Excludes a freestanding unit which was said to be “mothballed.”

Table 9: Average number of Exams per MRI (Hospital-Stationary)

Year	Total Utilization	# of Units Reporting	Average exams/unit
1996	20289	7.0	2898
1998	25303	7.0	3615
2000	35374	9.0	3930
2002	37448	10.0	3745
2004	40429	12.0	3369
2006	50596	14.3	3538
2007	52205	15.7	3325
2008	55881	16.7	3346
2009	55281	16.8	3291
2010	58158	15.8	3681
2011	59222	13.3	4453

Table 10: Average number of Exams per MRI (Hospital-Mobile)

Year	Total Utilization	# of Units Reporting	Average exams/unit
1996	1172	1.5	1141
1998	5313	2.1	2530
2000	11020	4.1	2688
2002	14152	5.3	2670
2004	13351	5.6	2384
2006	8615	3.1	2779
2007	8520	4.9	1739
2008	8678	4.9	1771
2009	8803	5.9	1492
2010	9572	6.0	1595
2011	9867	8.5	1161

Table 11: Average number of Exams per MRI (Freestanding)

Year	Total Utilization	# of Units Reporting	Average exams/unit
1996	4060	1.0	4060
1998	6613	1.0	6613
2000	17762	6.0	2960
2002	24129	7.0	3447
2004	41181	10.2	4037
2005	39437	10.5	3756
2007	39371	13.3	2960
2008	38338	13.0	2949
2009	40930	14.0	2924
2010	39104	14.0	2793
2011	42003	14.0	3000

Utilization by body section

The utilization by body section reported in calendar year 2011 survey showed the following trends:

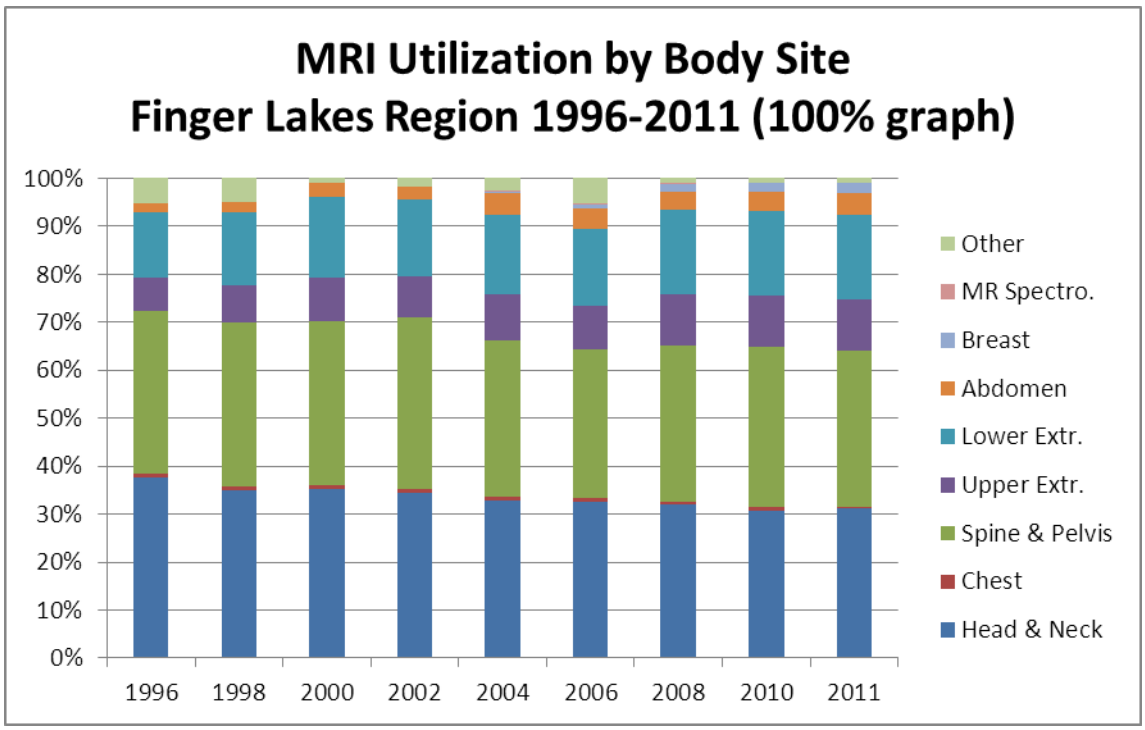
- A steady increase in breast scans since 2004
- A decline in MRI spectroscopy from levels observed in 2006-2007
- A steady increase in scans of the extremities
- A relative plateau in head and neck as well as spine and pelvis scans.

Figure 4 illustrates these findings.

The distribution of MRI procedures in the Finger Lakes region is similar to IMV's national findings[7]. The largest proportion of scans was completed in the head and neck categories, followed by the spine and pelvis (including the brain). Procedures performed on the lower and upper extremities accounted for 14% and 12% of the procedures nationally.

[7] IMV 2012 Report

Figure 4: Regional Utilization by Body Site, 100 percent graph



Tables 12 through 14 present the total numbers of MRI procedures by body section, each section as a percentage of the total, and the growth rate for each body section. Note, in Table 12, the body section figures may not add to the Total due to missing respondent data.

Table 12: Total Utilization by Body Section

Body Section	1996	1998	2000	2002	2004	2006	2008	2010	2011
Head & Neck	8044	11267	22561	25756	30875	33183	32722	32515	34363
Chest	178	290	604	702	677	735	670	950	394
Spine & Pelvis	7260	10991	21950	26897	30792	31662	33162	35569	36060
Upper Extr.	1456	2480	5810	6326	9074	9335	11071	11176	11815
Lower Extr.	2928	4930	10784	11970	15710	16384	17833	18765	19346
Abdomen	381	663	1768	2016	4062	4411	3853	4255	5129
Breast	-	-	-	-	391	761	1564	1872	2330
MR Spectro.	-	-	-	-	230	331	293	113	65
Other	1122	1584	678	1341	2395	5232	1086	990	980
Total	**26061**	**31204**	**64156**	**75729**	**94961**	**99114**	**102998**	**106975**	**111092**

Table 13: Percent of Total Utilization by Body Section

Body Section	1996	1998	2000	2002	2004	2006	2008	2010	2011
Head & Neck	30.9%	30.2%	35.2%	34.0%	32.5%	32.7%	33.9%	30.7%	30.2%
Chest	0.7%	0.8%	0.9%	0.9%	0.7%	0.8%	0.8%	0.9%	0.3%
Spine & Pelvis	27.9%	29.5%	34.2%	35.5%	32.4%	32.2%	32.1%	33.4%	31.7%
Upper Extr.	5.6%	6.7%	9.1%	8.4%	9.6%	9.6%	9.7%	10.5%	10.4%
Lower Extr.	11.2%	13.2%	16.8%	15.8%	16.5%	17.1%	15.9%	17.6%	17.0%
Abdomen	1.5%	1.8%	2.8%	2.7%	4.3%	4.4%	3.8%	4.0%	04.5%
Breast	-	-	-	-	0.4%	0.8%	1.5%	1.7%	02.1%
MR Spectro.	-	-	-	-	0.2%	0.3%	0.3%	0.1%	0.1%
Other	4.3%	4.3%	1.1%	1.8%	2.5%	1.1%	2.8%	0.9%	0.9%

Table 14: Total Utilization Annual Growth Rate by Body Section

Body Section	96-97	98-99	00-01	02-03	04-05	06-07	08-09	09-10	10-11	Total 96-11	Annual 96-11
Head & Neck	16.8%	35.0%	4.0%	-3.6%	-1.3%	-2.9%	-3.7%	2.0%	5.7%	427.2%	10.2%
Chest	34.3%	-3.4%	4.9%	-9.2%	21.5%	5.9%	4.6%	36.7%	-58.5%	221.3%	5.4%
Spine & Pelvis	24.0%	28.0%	3.7%	-0.5%	2.5%	2.7%	4.8%	4.3%	1.4%	496.7%	11.3%
Upper Extr.	27.1%	33.4%	-0.4%	3.4%	-1.3%	14.0%	0.5%	2.1%	5.7%	811.5%	15.0%
Lower Extr.	31.6%	33.1%	1.1%	16.9%	-0.2%	5.7%	0.5%	7.0%	3.1%	660.7%	13.4%
Abdomen	1.6%	36.7%	-2.7%	24.6%	-2.8%	-12.4%	-1.4%	14.0%	20.0%	1346.1%	18.9%
Breast	-	-	-	-	66.0%	56.0%	23.9%	-4.4%	24.5%	595.9%*	29.0%*
MR Spectro.	-	-	-	-	2.2%	46.5%	-24.9%	-47.7%	-42.5%	28.3%*	-16.5%*
Other	25.8%	-41.2%	69.4%	1.8%	26.4%	-78.7%	0.1%	-4.4%	-1.0%	40.9%	-12.0%
Total	**19.7%**	**19.4%**	**4.3%**	**2.2%**	**1.3%**	**1.7%**	**1.0%**	**1.4%**	**3.8%**	**426.3%**	**10.2%**

*Breast and MR Spectroscopy growth rate calculated utilizing data from 2004 to 2011

Payor Analysis

Table 15 describes MRI utilization by payer by respondent type. Notably, both mobile and stationary hospital sites have a higher proportion of Medicaid-paid procedures than freestanding sites (often due to insurance rules)

Table 15: MRI Service Utilization by Payer for 2011

Payer	Hospital Stationary	Hospital Mobile	Freestanding	Regional total
BCBS	27%	26%	29%	28%
Local HMOs	20%	17%	36%	27%
Other Commercial	12%	18%	11%	12%
Medicare	20%	23%	12%	17%
Medicaid	11%	10%	3%	8%
Workman's comp.	6%	4%	7%	6%
Private Pay	2%	2%	1%	1%
Others	2%	1%	0%	1%
Total	100%	100%	100%	100%

Table 16 provides information from the surveys on the proportion of MRI studies done on an outpatient basis. The proportion outpatient was near the lowest recorded, driven by declines in the use of hospital-based units for general outpatient exams. This may also reflect the effects of utilization management programs put in place by area insurance companies. These data are consistent with national trends report by IMV that 78% of all MRI procedures are performed on an out-patient basis[8].

In the Finger Lakes Region, the percentage of MRI procedures done for Emergency Department patients accounted for 10.1% of the exams completed on stationary hospital units and 8.3% of the exams completed on mobile hospital units. Overall, 5.4% of all MRI exams were completed on Emergency Department patients (data not show). However, these data may be incomplete; a few respondents were unable to provide data for Emergency department utilization at their facility.

Table 16: Proportion of MRI Exams Performed on Outpatient Basis

Unit Type	1996	1998	2000	2002	2004	2005	2006	2007	2008	2009	2010	2011
Hospital Fixed	84.8%	84.2%	81.8%	74.8%	80.7%	80.5%	80.5%	79.9%	77.3%	69.9%	80.3%	77.3%
Hospital Mobile	94.6%	94.1%	90.2%	94.2%	93.1%	93.0%	92.1%	90.1%	92.2%	87.7%	88.9%	86.4%
Freestanding	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
Combined			89.7%	86.1%	91.5%	90.6%	90.8%	93.1%	89.6%	83.4%	90.1%	87.7%

[8] IMV 2012 Report

Section Four: Capacity Analysis

Use Rate per Capita

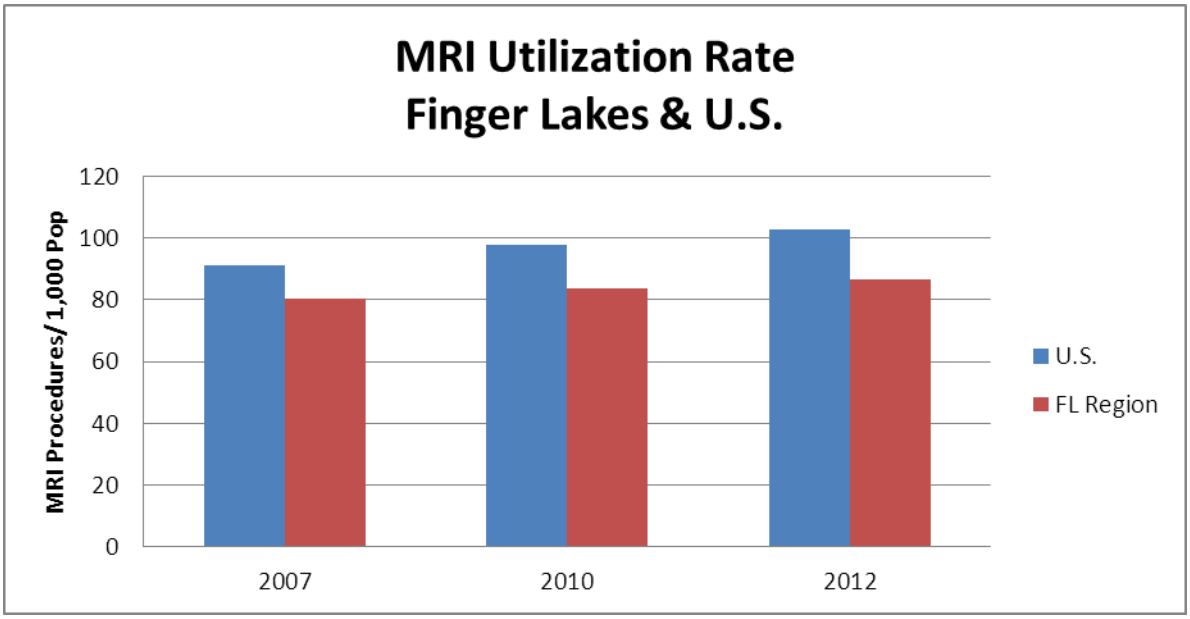
The analysis presented in this report has been a "demand" analysis. Given the current use or demand for MRI studies, how many units of capacity are needed? This assumes that all current use is clinically appropriate. That question is a clinical one, not within the FLHSA's jurisdiction, but perhaps addressed by the existing clinical and financial controls. We can get a glimpse, however, of whether the area's population is using more or less MRI service than the U.S. by comparing our use rate per capita to that of the entire country.

The 2012 MRI Benchmark Report provides the needed data for this analysis. In its report, IMV uses the data from approximately 7,800 hospital and non-hospital sites to extrapolate nationwide utilization rates for procedures performed through 2011[9].

Since 2004, the Finger Lakes Region's per capita rate has remained below the national utilization rate. With 86.8 MRI procedures per 1000 population in 2011, the Finger Lakes region is below the 2011 U.S. average of 102.7 scans per 1000 population.

In its 2012 report, IMV did not provide state-by-state estimates of MRI use. Thus, one can only compare regional use rates to national rates. While our regional rate has increased, it has done so more slowly than at the national level: Our regional use rate has increased by 8.1% since 2007, while the national rate has increased by 12.9% since 2007.

Figure 5: MRI Use Rates Per Capita



Data sources: U.S. IMV Ltd. 2007, 2010, 2012 MRI Benchmark reports
F.L. – FLHSA Annual Survey of MRI Facilities

[9] IMV 2012 Report

Need for MRI Capacity

Based on the current MRI utilization (111,092 total scans) within the Finger Lakes Region, it is possible to estimate future need for Monroe County, the Central Finger Lakes, and the Southern Tier.

Assuming various projected increases, MRI need for 2012 and 2013 would not surpass current operational and approved capacity for the 35.8 existing machines in the region. The current operational capacity and projected need for Monroe County, the Central Fingers Lakes and the Southern Tier are presented in Figures 6-8. As illustrated in Figure 6, the only subarea that may come close to surpassing current capacity is Monroe County: At standardized current capacity of 101,925 total scans, the 2013 maximum projection totals 106,617 scans assuming an unlikely annual growth rate of 17.5% per year from the 2011 total. A few of the Monroe hospitals and other facilities are approaching their rated capacity, however. The Central Finger Lakes is well within its current capacity in 2013, with a maximum of 16,575 projected scans versus a standardized current capacity of 20,275 scans. The Southern Tier is also projected to be within current capacity in 2013, with 27,138 scans projected as the maximum for 2013 and a capacity of 29,413 scans in the subarea. It is unlikely any additional capacity will be required in the next few years.

Figure 6: MRI Capacity and Projected Need: Monroe County

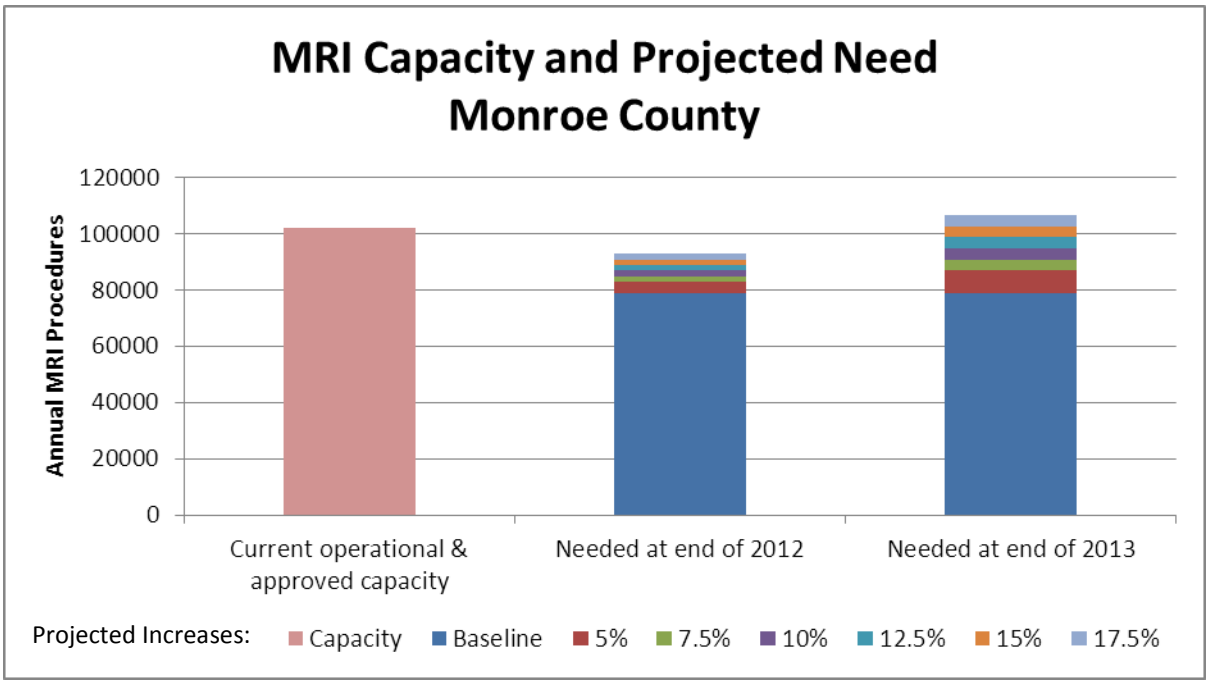


Figure 7: MRI Capacity and Projected Need: Central Finger Lakes

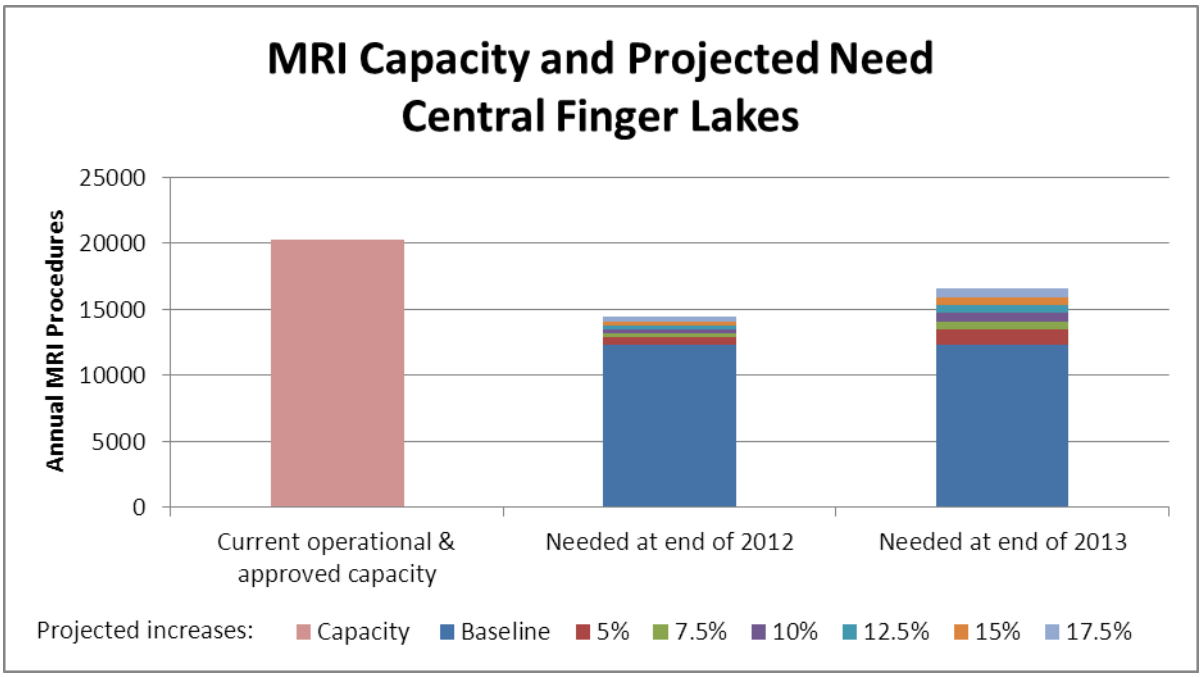
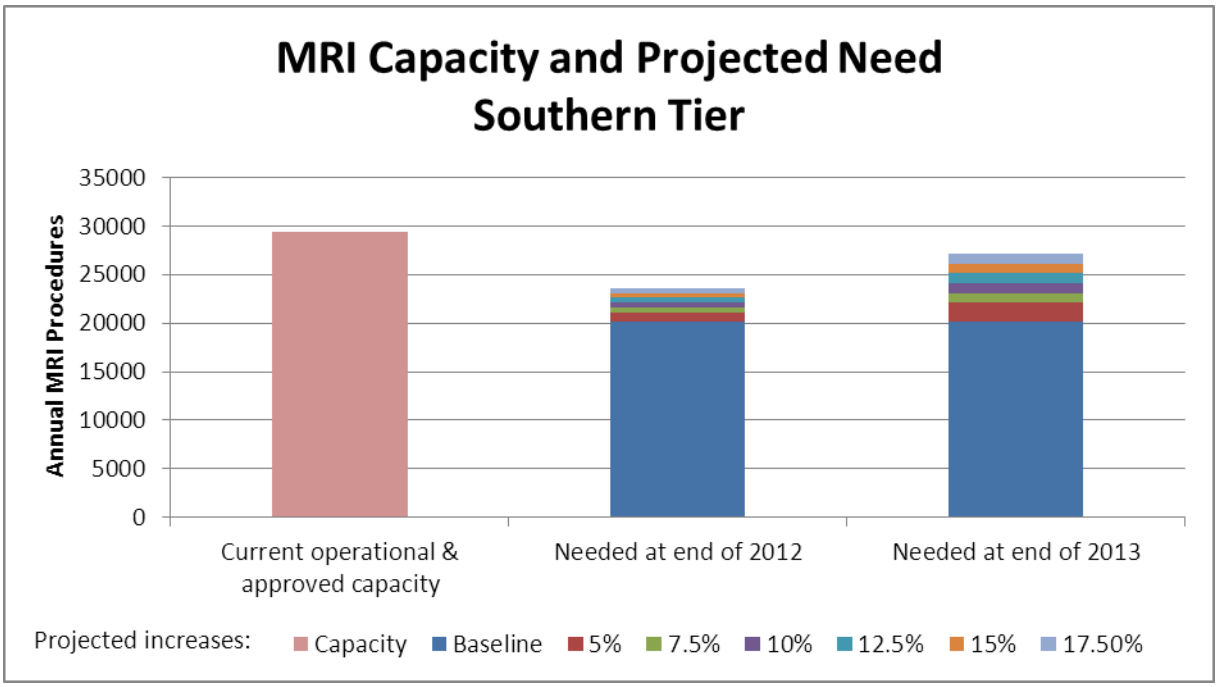


Figure 8: MRI Capacity and Projected Need: Southern Tier



FINGER LAKES REGION CT CAPACITY AND UTILIZATION REPORT, 2011

March 2013

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Contents

Executive Summary

On approximately a yearly basis, Finger Lakes Health Systems Agency surveys regional CT providers to assess if there have been changes in the inventory of CT scanners and their utilization. This assessment is undertaken to help assure that the region's population is appropriately served for CT services. The assessment which follows reports on CT inventory and utilization for calendar year 2011.

No additions to CT scanner capacity were made in the region in 2011, although there was one replacement unit installed. The scanners in the region are similar to what is used nationally in terms of age and capability of the machines.

It appears there is sufficient CT capacity to meet the region's needs for the foreseeable future. However, some additions may be needed at regional hospitals to assure that there is capacity to scan inpatients and Emergency Department patients, which can only be done in the hospital. Survey data disclosed that as much as 100% of some hospital scanner capacity may be dedicated to scans of hospital inpatient and ED patients, and some scanners which primarily serve ED patients are used for extremely high numbers of scans.

CT scans offer many benefits over other diagnostic tests and continue to be employed as the primary method for diagnosing many common conditions replacing other testing methods. The appropriate use of CT has been an important public health issue in recent years due to the risk of exposure to radiation associated with CT and also reducing costs. There have been several policy –based and clinical initiatives which may have altered CT utilization in 2011. In an effort to control imaging volume and costs, Excellus in 2007 contracted with CareCore National to manage Excellus' radiology benefit, and announced that physicians and other providers would be required to obtain prior authorization for all non-emergent, outpatient PET, CT, MRI, nuclear cardiology and nuclear medicine studies; in June 2008, the program was implemented. A prior-authorization program was also put in place by Preferred Care, now MVP. Simultaneous with the implementation of the prior authorization programs, the American College of Radiology began programs with both public and providers recommending reductions in radiation exposure. Approriate use of CT scans is emphasized as these scans expose patients to a greater dose of radiation than other imaging techniques . Lastly, in January 2011 there was a modification to the method used for reimbursement of abdominal and pelvic CT scans. Prior to January 1st 2011, abdominal and pelvic CT scans were coded using distinct CPT codes and were counted as unique procedures. After January 1st, the Centers for Medicare and Medicaid Services (CMS) mandated the use of new CPT codes which combined abdominal and pelvic CTs into one procedure.

Utilization of CT scanners in the 6 county Finger Lakes Region decreased by 10.9% between 2010 and 2011 which continues the decline that was observed in 2010. This decline parallels a national trend of slowed growth of CT utilization when compared to the immense growth experienced in the early 2000's.

However, the regional rates should be intepreted with caution, considering the modifications with the CPT coding and reimbursement for abdominal and pelvic CT scans intiated in 2011. In a separate analysis that disregarded abdominal and pelvic CT scans, the region experienced a 0.2% increase in overall utilization when compared to 2010 reports.

Section One: Introduction

This report describes the availability and utilization of CT scanners in the Finger Lakes region of New York[1]. Unless otherwise noted, the source of data is annual CT surveys conducted by the Finger Lakes Health Systems Agency (FLHSA), with the most recent data being from a survey begun in February of 2012 and including data from calendar year 2011. The information derived from the data will be used by the FLHSA in its roles as defined by the state Certificate of Need law and the Community Technology Assessment Advisory Board (CTAAB)[2], in order to provide recommendations to area health plans on the adequacy of CT capacity to meet the needs of local enrollees for this service. Unless indicated, data pertaining to areas outside of the Finger Lakes region is derived from the IMV Medical Information Division 2012 CT Benchmark Report. Additionally, unless indicated, regional aggregate data includes that provided by Veterans Affairs Medical Centers in Bath and Canandaigua.

Section Two: Capacity

Introduction

Finger Lakes Health Systems Agency has been involved with CT planning efforts since 1978, when there were 2 privately owned and 2 hospital-based CT services, all in Rochester. Early on, the Agency sought to promote optimal use of existing units and to prevent duplication of services. Still, by 1988, the region had 18 scanners, and CT was recognized by FLHSA as a standard diagnostic capability that should be available to all acute care hospitals.

Over the next 12 years, FLHSA utilized its adopted policy to review more than 20 CON applications for CT scanners (including replacements as well as additions). By 2004, interest by New York State Department of Health and area payors in CT capacity and utilization waned; as a result, the Agency stopped reviewing applications. In 2006, however, insurers requested the development of guidelines for and review of incremental CT capacity that would have the capability to image coronary arteries. While the insurers considered CT visualization of coronary arteries investigational at the time of their request, they acknowledged growing scientific evidence in support of this technological application.

Inventory

FLHSA surveyed all CT facilities within the Finger Lakes counties, with 28 out of 29 responding. As of December 2011, there are 39 CT scanners in the Finger Lakes region. Of the total, 28 units are hospital-based, while 11 CT scanners are located at freestanding imaging centers. One unit was upgraded to a new unit in 2011. No units are located in offices of doctors who do not practice radiology. All units in the region are fixed; there are no longer any identified mobile CT scanners.

Table 1 lists the CT sites in the region. Table 2 describes the manufacturer, and the number of slices each machine is capable of performing.

[1] The nine counties in the Finger Lakes region include Chemung, Livingston, Monroe, Ontario, Seneca, Schuyler, Steuben, Wayne, and Yates.

[2] CTAAB area includes Livingston, Monroe, Ontario, Seneca, Wayne, and Yates counties in the Finger Lakes region, plus Orleans, Genesee and Wyoming. Therefore, additional analysis is required for CTAAB review.

Table 1: Location and ownership of CT scanners in the Finger Lakes region

Region	Site Location	# Units	Ownership
Monroe County	Highland	2	Hospital
	Lakeside	1	Hospital
	Rochester General	3	Hospital
	Unity	1	Hospital
	Strong	6	Hospital
Central Finger Lakes	Clifton Springs	1	Hospital
	F.F. Thompson	1	Hospital
	Geneva General	1	Hospital
	Newark Wayne	1	Hospital
	Nicholas Noyes	1	Hospital
	Soldiers and Sailors	1	Hospital
	VAMC Canandaigua	1	U.S. Government
Southern Tier	Arnot Ogden	2	Hospital
	Corning	1	Hospital
	Ira Davenport	1	Hospital
	Schuyler	1	Hospital
	St. James Mercy†	1	Hospital
	St. Joseph's	1	Internal Medicine Associates of Southern Tier
	VAMC Bath	1	U.S. Government

Region	Site Location	Units	Ownership
Freestanding- Monroe County	Red Creek Drive	1	Borg & Ide
	Lattimore Road	1	Borg & Ide
	Clinton Crossings	1	Borg & Ide
	Hagen Drive	1	Borg & Ide
	Park Ridge	1	Borg & Ide
	Ridgeway	1	Borg & Ide
	Culver Road	1	Borg & Ide
	Cross Keys Park	1	Rochester Radiology
	Portland Avenue	1	Rochester Radiology
	Lac de Ville	2	University Medical Imaging

†2009 data

Table 2: Types of CT scanners in the Finger Lakes region

Region	Site name	Manufacturer	Slices	Notes
Monroe County	Highland	Philips	40	
	Highland	Philips	128	
	Lakeside	Toshiba	32	
	Rochester General	GE	16	
	Rochester General	GE	16	
	Rochester General	GE	64	
	Strong	Philips	16	
	Strong	Philips	16	
	Strong	Philips	64	
	Strong	Philips	64	
	Strong	Philips	64	
	Strong	Phillips	64	
	Unity	Philips	16	
Central Finger Lakes	Clifton Springs	Philips	16	
	F.F. Thompson	Philips	64	
	Geneva General	Philips	64	
	Newark Wayne	GE	16	
	Nicholas Noyes	Hitachi	64	Replaced in 2011
	Soldiers and Sailors	Philips	16	
	VAMC Canandaigua	GE	4	
Southern Tier	Arnot Ogden	Siemens	128	
	Arnot Ogden	Siemens	64	
	Corning	Siemens	64	
	Ira Davenport	Philips	16	
	Schuyler	GE	16	

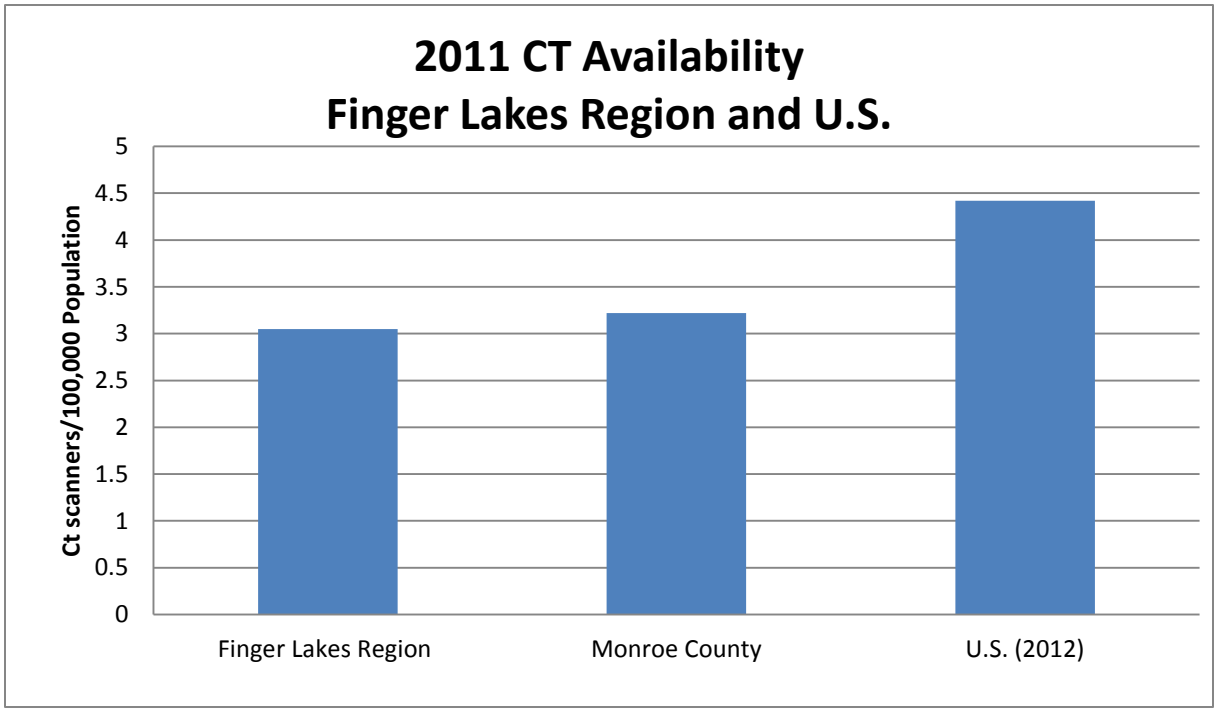
Region	Site	Manufacturer	Slices	Notes
Southern Tier (Continued)	St. James Mercy†	Philips	16	
	St. Joseph's (IMAST)	GE	16	
	VAMC Bath	Philips	64	
Monroe County Freestanding Centers	Red Creek Drive	GE	4	
	Lattimore Road	GE	4	
	Clinton Crossings	GE	64	
	Hagen Drive	GE	16	
	Park Ridge	GE	16	
	Ridgeway	GE	8	
	Culver Road	GE	16	
	Cross Keys Park	GE	4	
	Portland Avenue	GE	64	
	Lac de Ville	GE	64	
	Lac de Ville	GE	64	

†2009 data

Units per Population

The total 39 identified scanners represent 3.05 scanners for each 100,000 population. In contrast, there were an estimated 13,755 fixed scanners nationally in 2012, or about 4.42 CT scanners per 100,000 population[3],[4]

Figure 1: Comparison of number of CT scanners per population nationally and regionally



U.S. Census Bureau, American Community Survey Population Estimates Program 2011
IMV , Benchmark Report CT, 2012

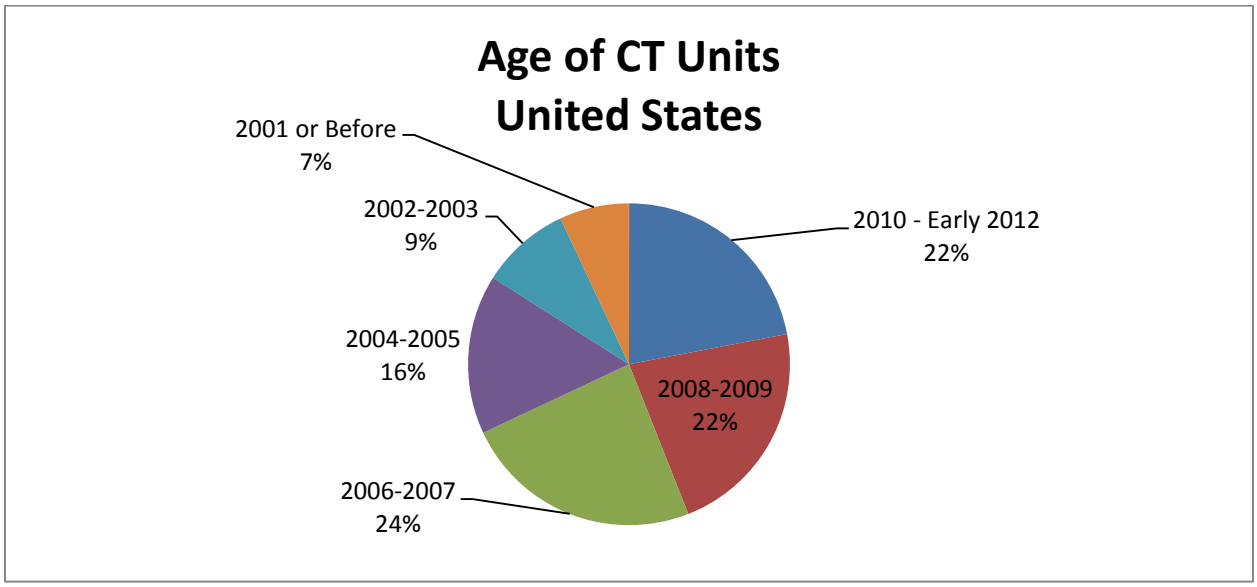
[3] U.S. Census Bureau, American Community Survey, 2011

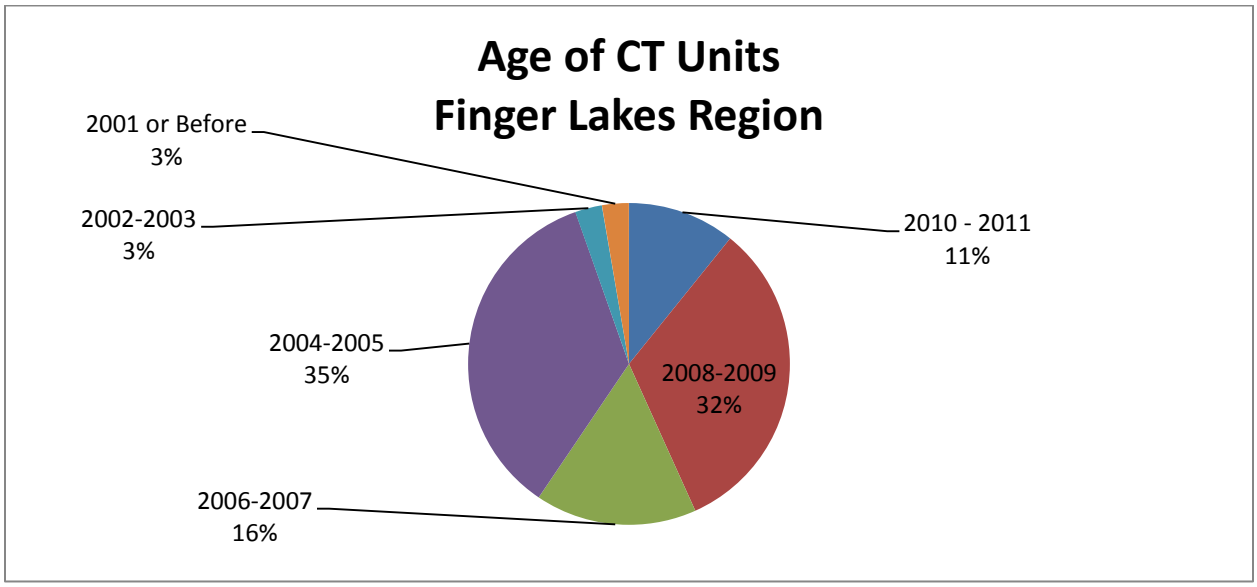
[4] IMV Benchmark Report, 2012

Age of Scanners

The age of the CT units in the Finger Lakes Region are similar to what is used nationally. Regionally, 43% of CT units were acquired between 2008 and 2011, compared with 44% nationally[5].

Figure 2: Comparison of age of CT equipment nationally and regionally



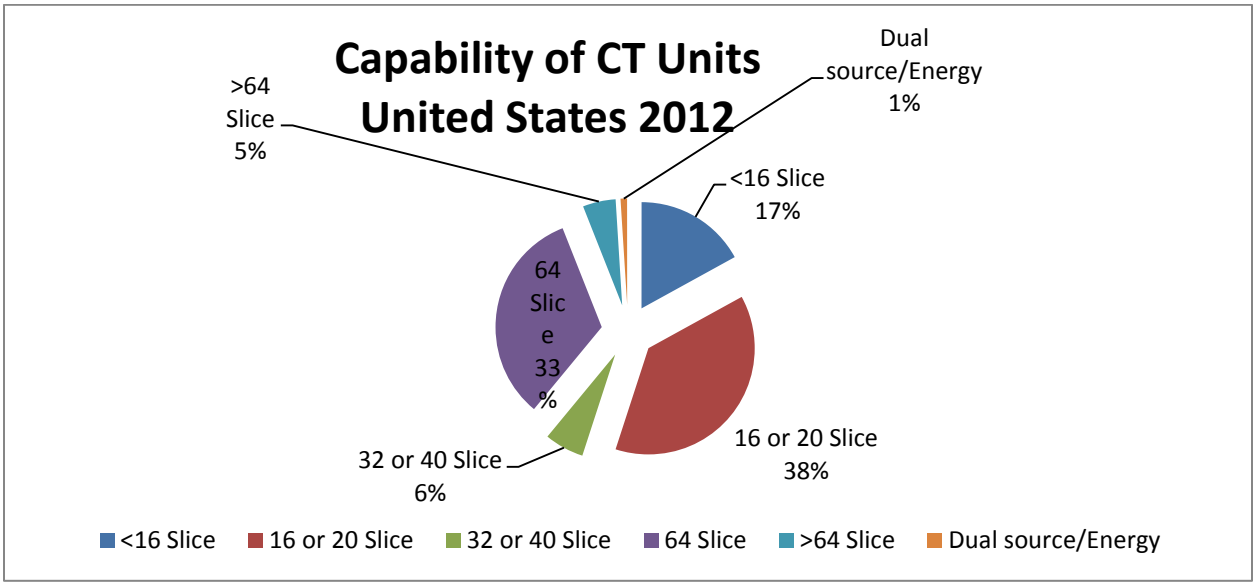


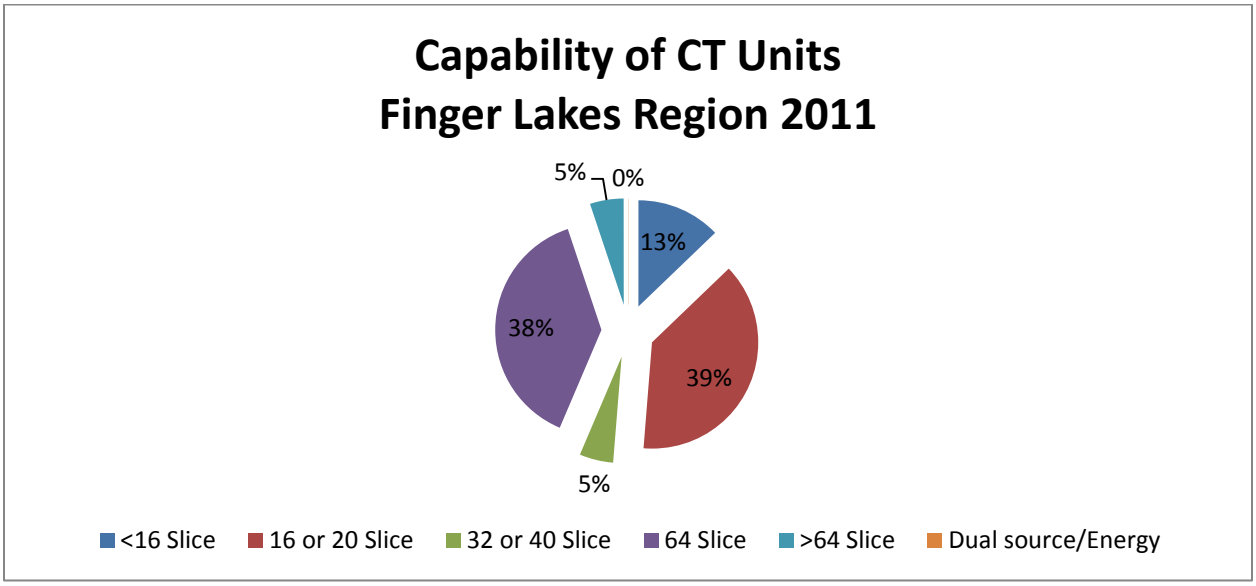
[5] IMV Benchmark Report, 2012

Capability of Scanners

CT scanners in the Finger Lakes region are of similar capability to what is available nationally. In the Finger Lakes region, 43% percent of CT scanners are 64-slice or greater; in comparison to 38% of CT scanners in the U.S. in 2012 had this capability (Figure 5 and Table 2)[6].

Figure 3: Comparison of capability of CT units nationally (2011) and regionally (2011)





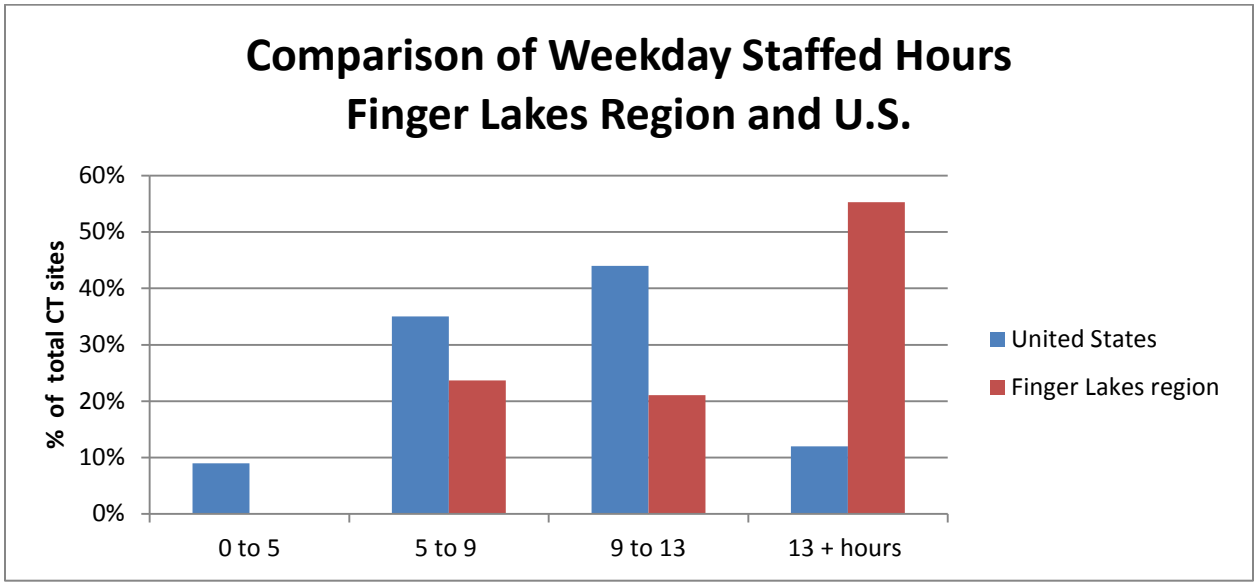
Source: IMV CT Benchmark Report, 2012; FLHSA CT Survey 2011.

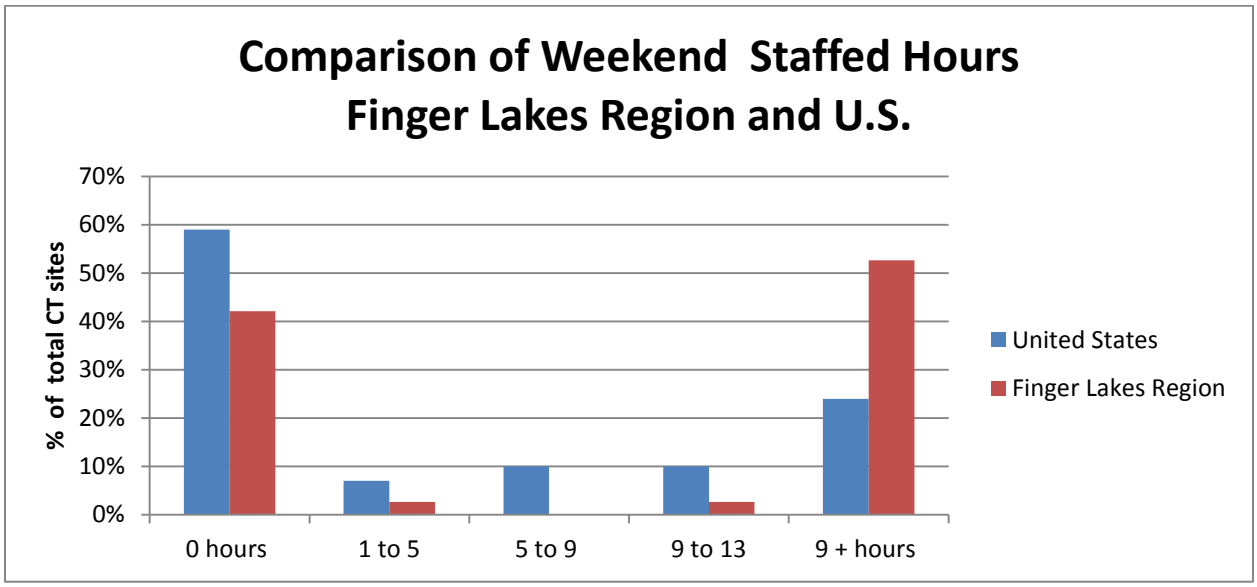
[6] IMV Benchmark Report, 2012

Staffing

CT facilities in the Finger Lakes region are generally staffed for more hours than CT sites elsewhere in the U.S. On weekdays, 74% of Finger Lakes sites are staffed a minimum of 9 hours compared with 56% nationally. More than half of Finger Lakes CT sites routinely staff on the weekends (those without assigned coverage may assign staff to be on call), while 41% of U.S. CT sites provide weekend coverage. In the Finger Lakes region, 55% of sites are staffed 9 or more hours on the weekends, compared with only 24% nationally[7].

Figure 4: Comparison of staffing at CT sites nationally and regionally





Source: IMV CT Benchmark Report 2012 and FLHSA CT Survey 2011

[7] IMV Benchmark Report, 2012

Section Three: Utilization

Utilization per Capita

During 2011, there were 295,946 scans recorded in the 9-county Finger Lakes region; of these, 187,920 occurred in Monroe County. This suggests a utilization of about 231.3 scans per 1,000 population regionally and a use rate of 252.0 CT scans per 1,000 population in Monroe County. The calculation for Monroe County does not take patient migration into account.

Based on survey data, IMV estimates a total national volume of CT scans at 85.3 million in 2011, at 4,833 hospital and 3,30 non-hospital locations. Utilizing population estimates, the estimated number of scans per 1,000 population is 273.8.[8]

Regional utilization was below the national rates in 2012. In previous years, the region's use of CT scans had exceeded national rates. The region's history of additional use of CT scans may have been attributed to local programs encouraging use of less expensive imaging technologies, such as use of CT instead of MRI scans. Over the past several years, regional growth has been slower than national trends. For example, CT utilization grew only 7% between 2006 and 2008 while national rates rose by 10%. There are several local and national factors which may have affected recent CT utilization in the region which are described below under the section "Constraints on Volume Growth" and "Changes in Clinical Guidelines."

Growth in Utilization

Incomplete reporting in earlier years makes it difficult to discern the long term growth rate of CT scanning in the Finger Lakes region. We do know that CT scanning in Monroe County increased 78 percent (from 164 scans/1,000 population to 293 scans/1000 population) from 2002 to 2008. This compares to a 51 percent increase nationally over the same period. The CT scanning growth rate in Monroe County peaked in 2006, however, with a 72 percent cumulative increase from 2002. Between 2006 and 2010, the Monroe rate increased only 8.8%.

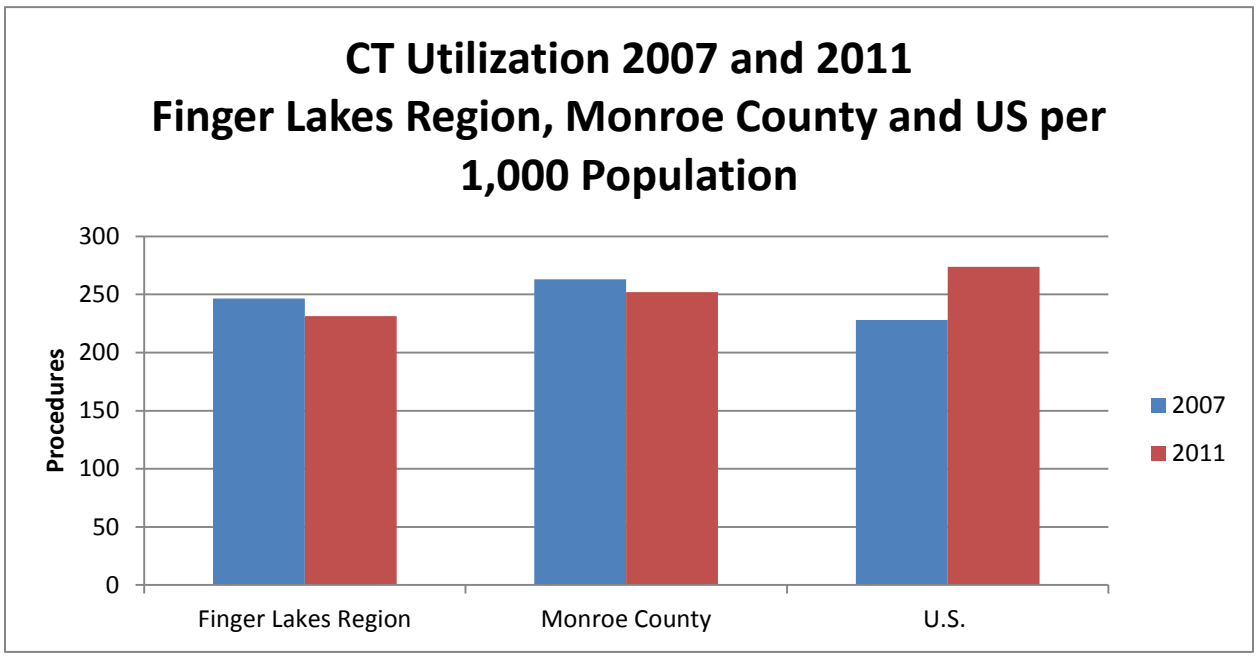
Similarly, in the last three years the Finger Lakes region experienced a plateau and then decrease in growth of CT scan utilization. From 2006 to 2011, the number of CT scans has decreased by 1.45%.

Meanwhile, the CT growth rate in the U.S. has continued to increase, however at markedly decreased rate from what was observed from 2000-2003. From 2010 to 2011, the national volume of CT scans increased 4%. National trends illustrate a reduction in annual growth compared to the higher rates recorded in the early 2000's. A recent study of the Medicare population demonstrated a 1.7% decreased in CT use in the Medicare population in 2010.[9]

[8] IMV Benchmark Report, 2012

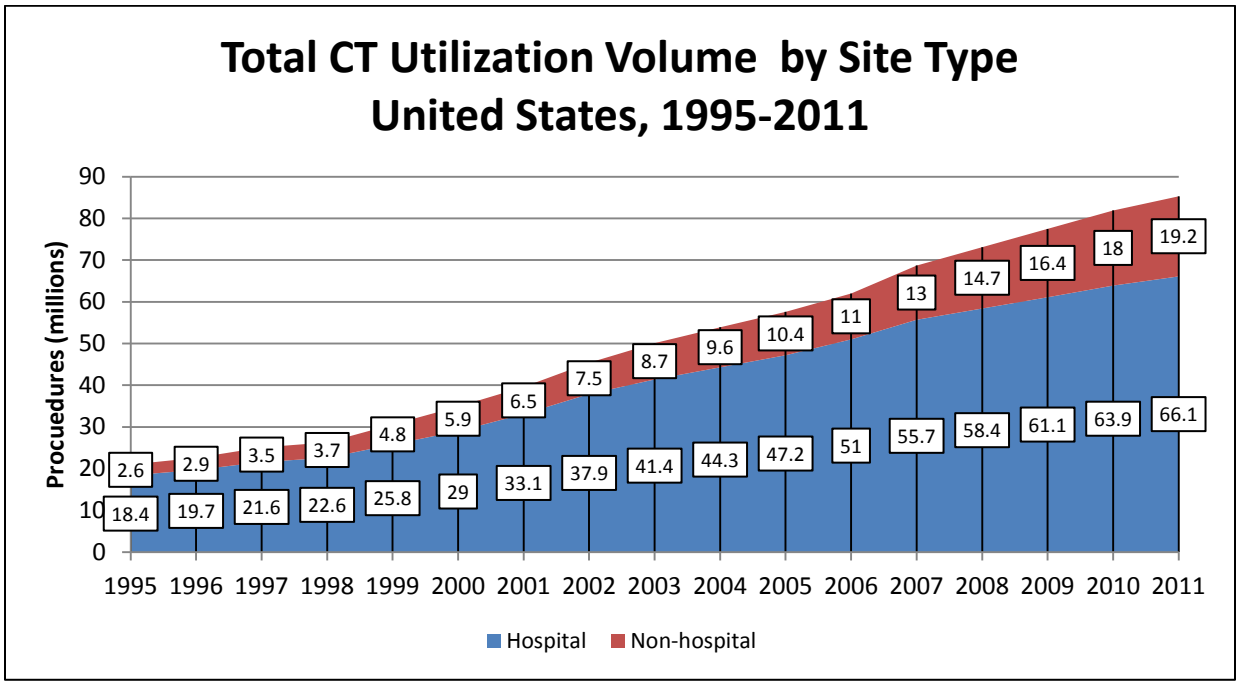
[9] Levin, D.C., Rao, V.M., & Parker, L. (2012). The recent downturn in utilization of CT: The start of a new trend? Journal of the American College of Radiology, 9, 795-798.

Figure 6: CT Utilization, 2007 and 2012 per 1,000 Population



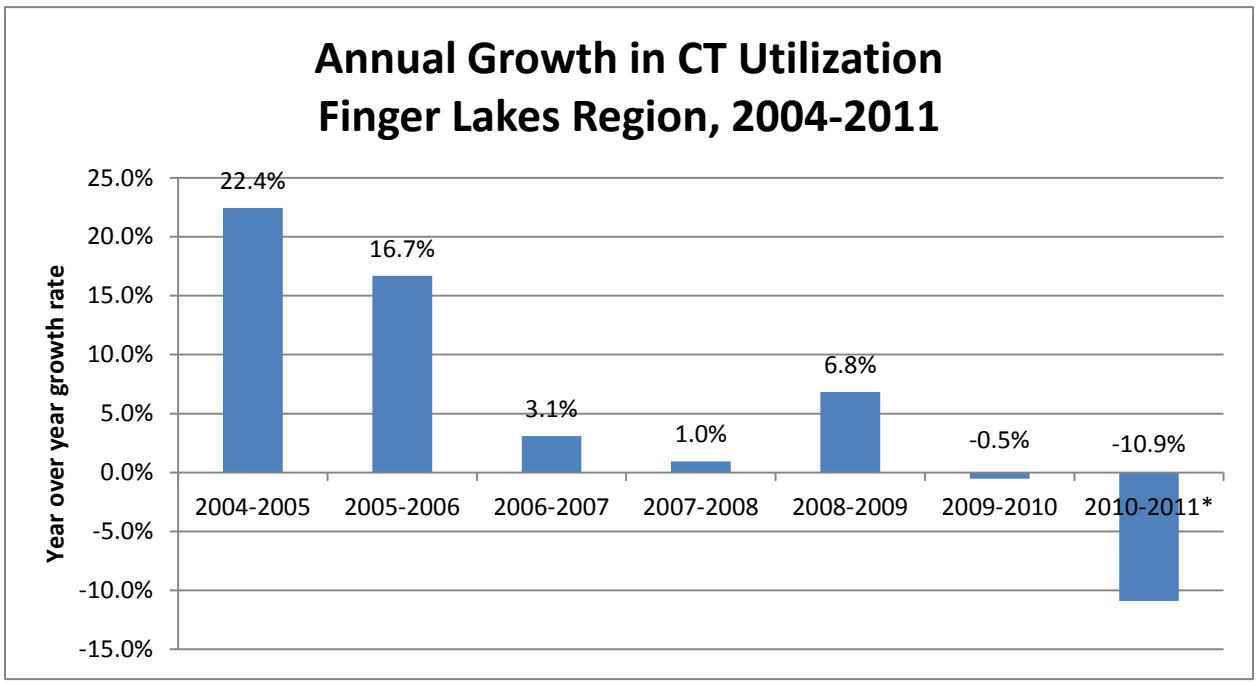
Data Source: U.S. Census Bureau, American Community Survey Population Estimates Program, 2012 and 2007
FLHSA CT survey 2011 and 2007
IMV, Benchmark Report CT, 2012 and 2007

Figure7: Total CT Utilization Volume by Site Type: United States, 1995-2012



Data Source: 2012 IMV National MRI Survey

Figure 8: Regional growth in CT utilization, 2004- 2011



*Includes abdominal and pelvic CT data which may be incomparable to previous years due to modifications in counting procedures. A 0.2% increase in utilization was reported when disregarding abdominal and pelvic CT data (see Constraints on volume growth on page 13).

Constraints on Volume Growth

In an effort to control imaging volume and costs, Excellus in 2007 contracted with CareCore National to manage Excellus' radiology benefit, and announced that physicians and other providers would be required to obtain prior authorization for all PET, CT, MRI, nuclear cardiology and nuclear medicine studies; in June 2008, the program was implemented. A prior-authorization program was also put in place by Preferred Care, now MVP.

Simultaneous with the implementation of the prior authorization programs, the American College of Radiology and other professional societies expressed concern for the total amount of ionizing radiation to which Americans were being exposed. A broad community-wide effort to reduce radiation exposure was initiated in this region. And with the continuing rise in the cost of health insurance, policies with larger co-payments shifted larger portions of imaging costs to the consumer; with the rise in high-deductible plans, many consumers became liable for the entire cost of services.

The Community Technology Assessment Advisory Board (CTAAB) also plays a role in supporting the thoughtful acquisition of new healthcare technology and services in the community. CTAAB is a review board in the Finger Lakes Region dedicated to assessing community need for expanded or new services, technology or capital expenditures. Applications to add CT scanners in the region would be reviewed by

CTAAB. The Board reviews a request to determine if the service is necessary considering issues such as geography, cost effectiveness and quality of care. The CTAAB review process is intended to reduce duplicative services and ensure quality care is maintained. This review process contributed to the region having fewer CT units per capita when compared to national reports.

In 2011 there was an update in the application of Current Procedural Terminology (CPT) codes for abdominal and pelvic CT scans. Prior to January 1st 2011, abdominal and pelvic CT scans were coded using distinct CPT codes and were counted as unique procedures. After January 1st, the Centers for Medicare and Medicaid Services (CMS) mandated the use of new CPT codes which combined abdominal and pelvic CTs into one procedure.

Changes in Clinical Guidelines

CT scans offer many benefits over other diagnostic tests and continue to be employed as the primary method for diagnosing many common conditions and has replaced other modes of testing. For example, CT has been found to be more accurate than ultrasound for diagnosing appendicitis[10]. Experts advocate for the use of CT if the diagnosis of appendicitis is uncertain or there is suspicion of a mass or perforation with abscess[11]. CT is also the preferred method for detecting other conditions including pulmonary embolism[12] and renal stones[13,14].

These changes in environment, clinical practice and policy have contributed to changes in use patterns and the volume of CT completed in the region. .

Volume

Since 2004 to 2005, there has been a steady decline in the growth of CT volume. Between 2004 and 2005 there was a 22% increase in total volume, in contrast between 2008-2009 CT volume increased only by 6.8%. This downward trend has persisted through 2011 and parallels the results of national studies (see Figure 6).

In 2011, Monroe county hospitals and free-standing facilities reported a 11.2% decline in the number of scans completed when compared to 2010. In 2011 within Monroe County, there was a 12.8% decrease in CT scan volume at hospital facilities and a 3.1% decrease in volume at free-standing facilities.

Similar declines in utilization were reported in the Central Finger Lakes counties and the Southern Tier counties with decreases of 17.2% and 4.2% respectively. Excellus and MVP have a similar joint market

[10] Terasawa, T., Blackmore, CC., Bend, S., & Kohlewes, R.J. (2004). Systematic review: Computed tomography and ultrasonography to detect acute appendicitis in adults and adolescents. Annals of Internal Medicine: 141 (7); 537-546.
[11] Paulson, E.K., & Kalady, MF & Pappas, T.N. (2003). Suspected appendicitis. New England Journal of Medicine: 348: 236-242.
[12] Stein PD, Fowler SE, Goodman LR, et al. (2006). Multidetector computed tomography for acute pulmonary embolism. New England Journal of Medicine; 354(22):2317–2327.
[13] Miller, O.F., Rineer, S.K, Reichard, S.R., et al. (1998). Prospective comparison of unenhanced spiral computed tomography and intravenous urogram in the evaluation of acute flank pain. Urology: 52: 982-987.
[14] Chen, M.Y.M., Zagoria, R.J., Saunders, H.S., & Dyer, R.B. (1999). Trends in the use of unenhanced helical CT for acute urinary colic. American Journal of Roentgenology: 173:1447-1450.

in the Central counties as in Monroe, while they likely have a lesser market presence in the Southern Tier.

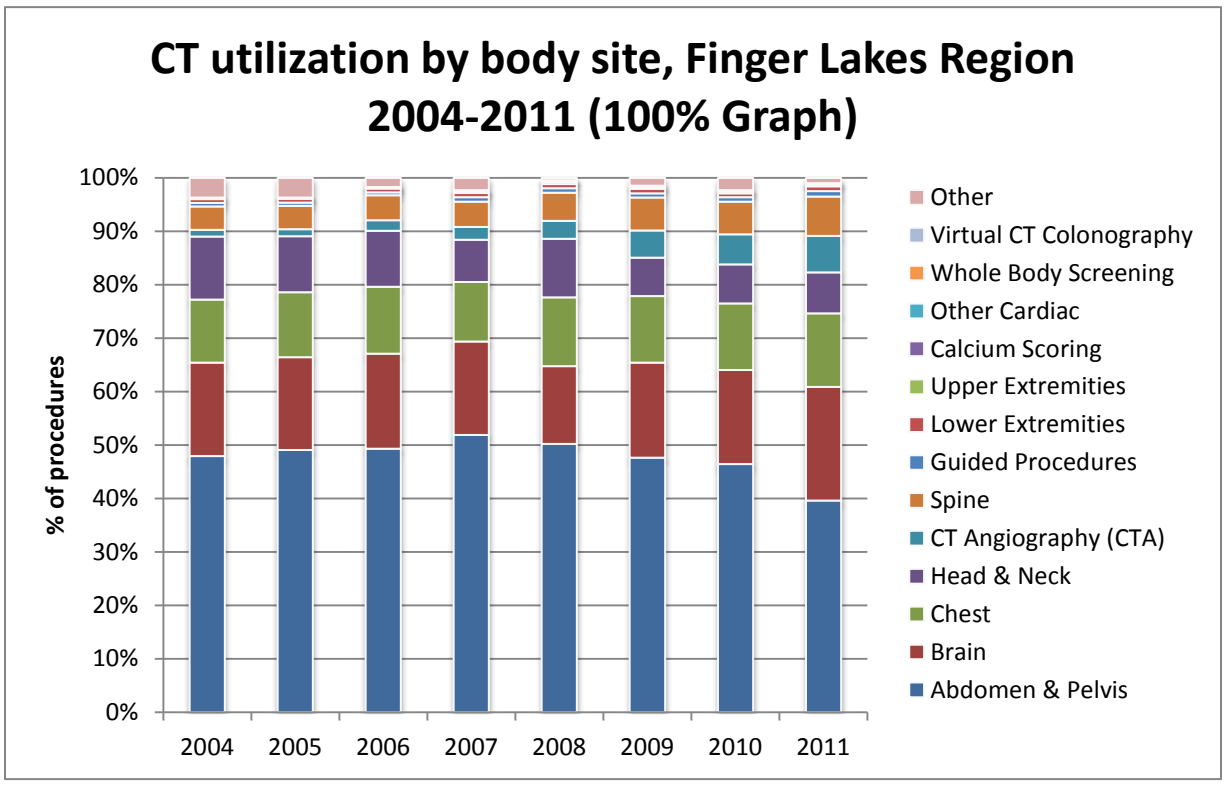
The modifications in CPT codes for abdominal and pelvic CT scans altered how procedures are counted in the region which makes it difficult to create equal comparisons between 2011 and previous years. We completed an analysis of CT utilization in the region removing scans completed on the abdomen or pelvis. This analysis revealed a 0.2% growth in utilization compared to 2010. The Monroe county hospitals and freestanding units experienced an overall 0.8% volume growth when disregarding abdominal and pelvic CT scans. Similarly, the Southern Tier counties also had a 0.99% increase in volume when compared to 2010, while the Central Finger Lakes Counties experienced a 3.4% decrease in utilization.

Body Section Scanned

During the 2004-2010 period, the aggregated percent of total CT utilization by body section has remained relatively constant. Specifically, CT scans of the abdomen and pelvis account for 47-52 percent of use, followed by the brain (17 percent), chest (12-13 percent), and head and neck (8-11 percent). All other body sections combined account for 10-12 percent of all CT studies (CT angiography, spine, guided procedures, extremities, calcium scoring, other cardiac, whole body screening, virtual colonoscopy, and others). In 2011, there was a decrease in the percentage of CT scans of the abdomen and pelvis compared to previous years. This represents a 22.4% decrease from the 2010 survey. As mentioned above, the variation between 2011 and previous years can likely be attributed to modifications in the reimbursement structure for abdominal and pelvic CT scans that went into effect on January 1st 2011. The new Current Procedural Terminology (CPT) codes combine abdominal and pelvic scans into one procedure. In the past, a CT of the abdomen and CT of pelvis were considered as two separate exams, under the new coding structure, they are now only 1 exam.

CT scans of the brain accounted for 21.3% of all procedures; which is an increase of nearly 10% from 2010. From 2005-2009 there had been a growth of cardiac studies, calcium scoring and virtual colonoscopy, however in 2010 and 2011 marked increases in these types of scans were not observed. There was a modest increase (7.1%) in the number of “Other Cardiac” studies. On the other hand, whole body screening CT, prevalent in some areas of the nation and sometimes provided on a cash basis by itinerant vendors but of questionable medical use, has not been reported performed by any regional CT scanner between 2004 and 2011.

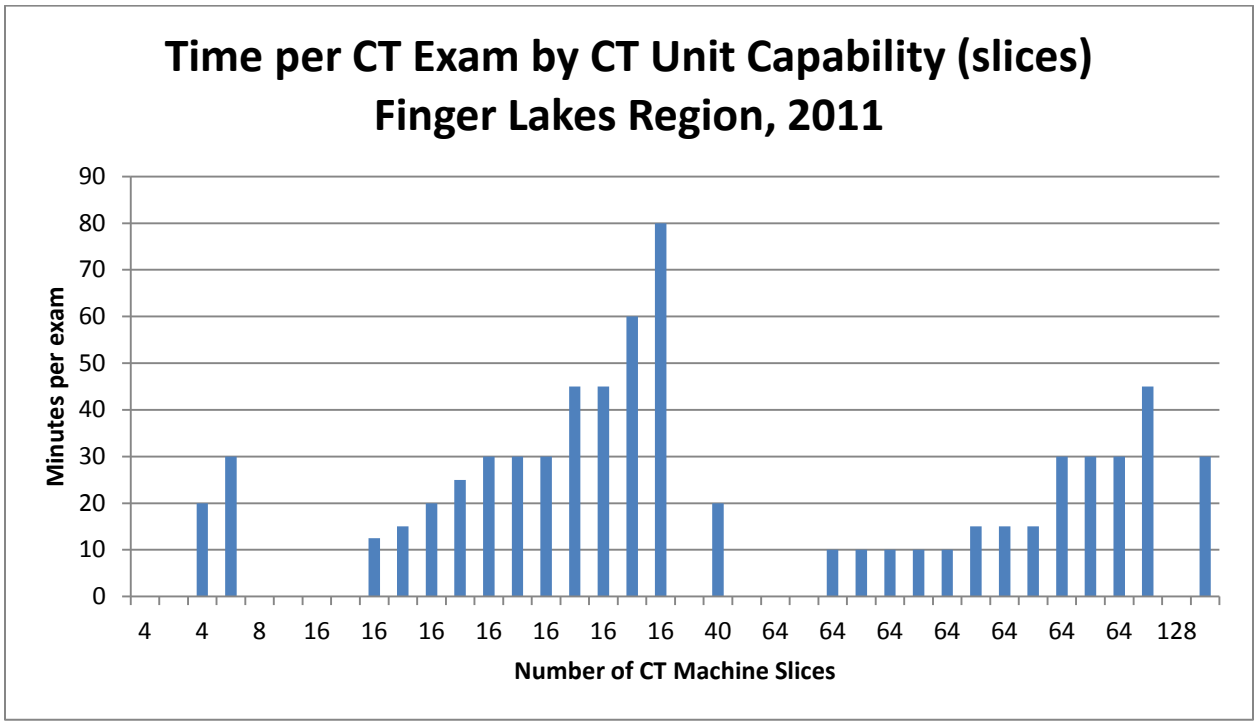
Figure 9: CT utilization by site, Finger Lakes region, 2004-2008 (100% graph)

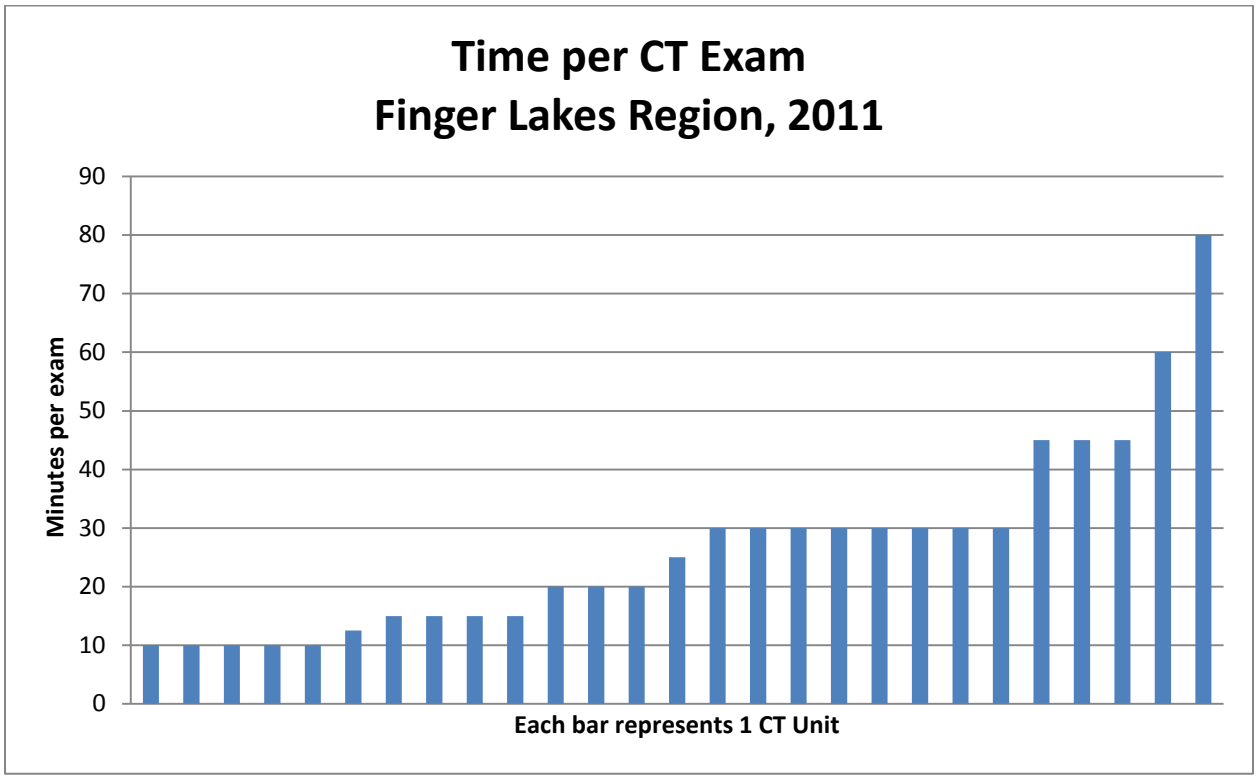


Scanning Time

Most area CT providers estimate that a scan takes between 10 and 30 minutes; although some units have an estimated through-put of one patient every 30 minutes, a few have through-put even lengthier. Based on the survey data, one cannot definitively correlate the number of slices with the length of scan time. Even among the 16-slice units, considerable variation exists (range 10-80 minutes), and at one hospital with multiple identical units, time per scan varies (range 30-60 minutes) based on the primary clinical use of each scanner.

Figure 10: CT scanning times and number of slices





Data Source: 2011 FLHSA Survey of CT providers; data reported for 27 of 39 units

While advanced CT scanners are faster than those of older technologies, one cannot assume that more slices results in concomitant higher productivity per scanner. In part, this is because of the fixed time to bring the patient to the scanner and position him or her for the examination. This is illustrated in Table 3 below. Patient acuity and case complexity also have a considerable impact on the length of scanning time.

Table 3: Estimated patient throughput times

A	B	C	D
Patient positioning (min)	**Scan Time (min)**	**Total exam time (min)** (A + B =C)	**Number of exams possible/hour** (60/C=D)
15	15	30	2
15	10	25	2.4
15	5	20	3
15	1	16	3.75
15	0.5	15.5	3.87

Potential Capacity

If one considers a scanner performing 3 to 4 scans per hour and a schedule of 12 hours per day/6 days per week (and obviously some of the region's units are used more intensively than that), a capacity per unit of 11,000 to 15,000 is theoretically possible. Some units in the region achieve that level of throughput; some substantially exceed that capacity.

Capacity vs. Demand

During 2011, there were 295,946 scans recorded in the 9-county Finger Lakes region; of these, 187,920 occurred in Monroe County. Based on 39 CT units, there was an average of over 7,580 scans per machine. However, the units at the VA facilities were only used for 1,200 and 2,700 scans; the balance of the region's CT scanners produced an average of 7,890 scans. There was a wide range of volume exhibited, ranging from under 2,000 exams on units which primarily are used for guided procedures or on a specific patient population, to 2,000-4,000 on some less-used freestanding units, to 8,000-12,000 for "average" hospital installations, to 12,000 to 17,000 for units which primarily serve Emergency Department patients and inpatients.

Several of the CT units in the region are not for general use; they are dedicated to a special patient population (e.g. Veteran's administration, smaller regional hospital) or used primarily for a specific scan type (e.g. guided procedures). To estimate the region's CT capacity, we posit that there are 31 "general" CT scanners in the region could each produce about 10,000 procedures per year. Based on the utilization reported in 2011 at the 31 "general" scanners, a growth of 14-16% utilization could be experienced before exceeding capacity.

It is important that hospitals have adequate capacity to perform the CT exams that can only be performed in the hospital – exams on inpatients and on Emergency Department patients. Information was provided in the survey on the mix of patients (outpatient, inpatient, ED). In some responses, these categories are not mutually exclusive, as most ED patients are also outpatients. Table 4 displays the trend in inpatient versus outpatient scans. Table 5 provides information collected on numbers of scans performed for ED patients.

Table 4: Proportion of CT Exams Performed on Outpatients

Facility type	Year							
	2004	2005	2006	2007	2008	2009	2010	2011
Urban hospital	54.6%	57.1%	51.4%	-	-	61.2%	30.3%	21.5%
Rural hospital	68.7%	69.3%	67.8%	-	-	52.4%	44.7%	40.3%
Freestanding	100.0%	100.0%	100.0%	-	-	99.8%	99.8%	100%
Combined	64.1%	67.1%	66.0%	-	-	65.5%	43.3%	41.9%

Table 5: Proportion of CT Exams Performed on Emergency Department Patients

Facility type	2010		2011	
	Count	%	Count	%
Urban hospital	67,146	35.9%	70,675	55.7%
Rural hospital	26,432	39.0%	32,542	48.7%
Freestanding	0	0.0%	0	0.0%
Combined	93,578	36.0%	103,217	45.5%

One can deduce that the vast majority of hospital-based CT scanners in urban areas (Rochester, Elmira) are used for inpatients or ED patients (i.e., approximately 20% of scans are for outpatients, and 55% of scans are for ED patients, suggesting 25% are for inpatients). In urban areas, freestanding scanners provide the bulk of outpatient scans. In more rural areas, the hospitals provide access to CT for both hospital patients (inpatient, ED) and referred outpatients.

Section Four: Access

Geographic Access

There are no specified geographic access standards for CT services in New York State. Instead, the New York State Department of Health bases need for CT services on utilization[15].

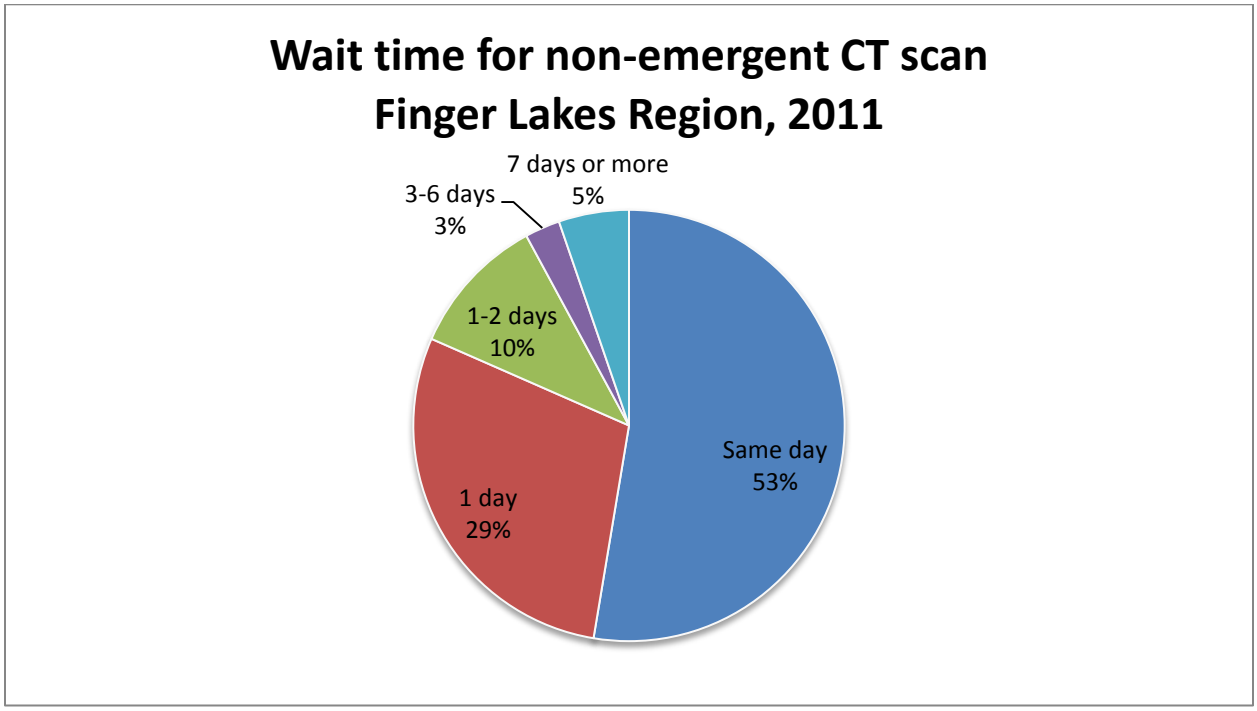
[15] Personal communication with J. Milliren, August 6, 2007.

All hospitals within the Finger Lakes region provide CT scanning services. All residents are within 30 minute travel to a CT scanner. Thus, the region is well served geographically for this service.

Wait Time to Access CT

A measure of whether there is sufficient capacity to provide a medical care service is how long a potential patient must wait to obtain the services. The current survey provides information on wait time for both emergency and routine services. Respondents almost exclusively indicated that an emergent patient can be evaluated on the day of the request, often within minutes of the request. There was one exception at a VA unit that reported a 1 day waiting period for emergent scans. Non-emergent patients can be scanned within one day at over 80 percent of facilities. There are two notable exceptions to this open availability: the VA Medical Centers in Bath and Canandaigua can have up to a 7- to 10-day wait for a non-emergent CT scan. Reported wait times were not independently verified.

Figure 11: Wait time for non-emergent CT scan: Finger Lakes Region, 2011



Data sources: FLHSA CT Survey, 2011. Information provided for 38 CT units

Financial Access

Not all respondents provided information about revenue sources for CT studies. Based on the data received, 25% of CT scans are covered by Medicare, while 55% are covered by private insurance. Private payments cover 3 percent of CT scans in the region. Regionally, Medicaid provides 10 percent of CT revenue. However, Medicaid accounts for 11 percent of hospital CT activity compared with only 2 percent of CT for freestanding imaging centers.

Section Five: Quality and Patient Risk

While improved technology enables clinicians to better image body structures, 3D imaging represents a paradigm shift with a significant learning curve for practitioners. The interpretation of advanced CT scans, in particular non-invasive imaging of the coronary arteries, is technically complex and requires specialized credentialing by the American College of Cardiology or the American College of Radiology. At least in early periods, some advanced imaging may not be available on a 24/7 basis even at tertiary centers.

Of greater importance, studies utilizing the newest technology come with hazards for some patients. First, iodine based radiopaque contrast media may be injected to better delineate the structures being examined. The contrast agent is somewhat toxic to the kidneys, especially for those individuals with impaired kidney function and diabetics. Second, a CT scan exposes patients to ionizing radiation[16], classified as carcinogenic by the World Health Organization, the Centers for Disease Control and Prevention and the National Institute of Environmental Health Sciences. The dosage of radiation delivered with CT scanning is far greater than with a standard x-ray, and multi-slice CT scanners deliver higher doses of radiation than single-slice scanners. It is has been estimated that while "CTs make up only 12 percent of all medical radiation procedures, they deliver almost half of the estimated collective dose of radiation exposure in the United States" (Rabin, 2007).

As diagnostic imaging replaces natural background radiation as the leading cause of human exposure to radiation, increasing attention has been focused on its potential to induce cancer. Einstein et al. (2007) estimated the lifetime attributable risk (LAR) of cancer associated with radiation exposure from 64-slice CT coronary angiography. Their study suggested that the risks were particularly high for women and younger patients.

In response to these concerns, many radiology providers are employing CT imaging techniques that reduce radiation yet have been shown to not seriously degrade image quality and diagnostic value. Newer scanners will have some of these techniques built in; local providers should seek those scanners at time of needed replacements.

In this region, the provider community has used the regional health data exchange to avoid duplicate scanning and has developed guidelines on when CT studies should and should not be repeated in an effort to reduce overall radiation exposure.

Section Six: Conclusions

In this inventory of CT scanners in the Finger Lakes region, available data indicate that, overall the area is not underserved and regional scanners are accessible. Findings suggest that, at this time, there is no area-wide need for additional CT scanner capacity:

- The region has CT scanner equipment that is similar to what is used nationally with regards to age and scanning capability;

[16] While techniques can reduce the radiation delivered, CT scans may deliver radiation loads of 2-12 millisieverts (abbreviated mSv, a standard unit of radiation dose); in comparison, a standard chest x-ray delivers about 0.04 to 0.10 mSv and the average annual background radiation in the U.S. is 3 to 3.6 mSv. Per the U.S. Food and Drug Administration, a dose of 8 to 12 mSv may be associated with an increase in lifetime risk of fatal cancer of approximately 1 chance in 2000. Multiple scans, such as in "annual physicals," pose substantial cumulative risk. For further information, see R.C. Rabin report listed in bibliography.

- In recent years, regional utilization has stayed fairly constant, even decreasing slightly in 2010 and 2011, while national utilization rates have increased. From 2006 to 2010, the Finger Lakes region experienced a 11% increase in utilization, compared to a 42% increase in the four previous years;

- In 2011, there were modifications to the coding and billing procedures used for abdominal and pelvic scans. Abdominal and pelvic CT scans were bundled together into 1 procedure which generated an artificial but noticeable decrease in the number of scans reported. Future analysis of CT utilization and capacity planning must take these changes into account when calculating trends and using historical data.

- Use of each existing scanner, approaching 7,580 scans per unit. However, the average is:
  - skewed higher by very high use at some of the larger hospitals in the region;
  - well within the potential capacity of newer units (11,000 to 15,000 scans, calculated in the Potential Capacity section on page 17);

- Wait times to obtain a routine, non-emergent CT scan are within 1 day at over 80 percent of facilities.

Future surveys may need to account for indications that require longer scanning times, such as image-guided biopsies, in order to consider modification of the finding of no need for additional capacity.

The decision to utilize advanced CT technology should continue to weigh the benefits against potential risks. Work in the community to monitor the evidence and advocate for appropriate utilization need to continue

References

Chen, M.Y.M., Zagoria, R.J., Saunders, H.S., & Dyer, R.B. (1999). Trends in the use of unenhanced helical CT for acute urinary colic. American Journal of Roentgenology: 173:1447-1450.

Einstein, A.J., M.D., Henzlova, M.J., M.D., & Rajagopalan, S., M.D. (2007). "Estimating Risk of Cancer Associated With Radiation Exposure From 64-Slice Computed Tomography Coronary Angiography." *Journal of the American Medical Association, 293* (3), 317-323.

Finger Lakes Health Systems Agency (2002-2009). Computed tomography survey. Unpublished raw data.

Finger Lakes Health Systems Agency (1981). CT planning and review guidelines (Available from FLHSA, 1150 University Avenue, Building 5, Rochester, NY 14607).

Finger Lakes Health Systems Agency (1988, July 21). CT planning and review guidelines (Available from FLHSA, 1150 University Avenue, Building 5, Rochester, NY 14607).

Imaginis Corporation (2007). "Brief history of CT." Retrieved June 19, 2007 from http://www.imaginis.com/ct-scan/history.asp

IMV Medical Information Division, Inc. (2006). Benchmark Report CT 2006. DePlaines, IL.

Johns Hopkins Medicine (2007, March 26). "Johns Hopkins housing and testing only 256-slice CT scanner in North America." Retrieved June 19, 2007 from http://www.hopkinsmedicine.org/Press_releases/2007/03_26b_07.html

Levin, D.C., Rao,V.M., & Parker, L. (2012) The recent downturn in utilization of CT: The start of a new trend? Journal of the American College of Radiology, 9, 795-798.

Mettler, F.A., Huda, W., Yoshizumi, T.T., & Mahesh, M. (2008). Effective doses in radiation and diagnostic nuclear medicine: a catalog. Radiology; 248 (1): 254-263.

Miller, O.F., Rineer, S.K., Reichard, S.R., et al. (1998). Prospective comparison of unenhanced spiral computed tomography and intravenous urogram in the evaluation of acute flank pain. Urology: 52: 982-987.

Paulson, E.K., & Kalady, M.F., & Pappas, T.N. (2003). Suspected appendicitis. New England Journal of Medicine: 348: 236-242.

Rabin, R.C. (2007, June 19). With the rise in radiation exposure, experts urge caution on tests. Retrieved August 1, 2007 from http://www.nytimes.com/2007/06/19/health/19cons.html

Siemens AG (2007). "Computed tomography – Somatom definition." Retrieved June 19, 2007 from http://www.medical.siemens.com/webapp/wcs/stores/servlet/ProductDisplay~q_catalogId~e_-11~a_catTree~e_100010,1007660,12752,1008408~a_langId~e_-11~a_productId~e_168189~a_storeId~e_10001.htm

Stein P.D., Fowler S.E., Goodman L.R., et al. (2006). Multidetector computed tomography for acute pulmonary embolism. New England Journal of Medicine; 354(22):2317–2327.

Terasawa, T., Blackmore, C.C., Bend, S., & Kohlewes, R.J. (2004). Systematic review: Computed tomography and ultrasonography to detect acute appendicitis in adults and adolescents. Annals of Internal Medicine: 141 (7); 537-546.

U.S. Food and Drug Administration, Center for Devices and Radiologic Health (2007). "What are the radiation risks from CT?" Retrieved January 16, 2007 from http://www.fda.gov/cdrh/ct/risks.html http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm

U.S. Government (2006, January 26). Congressional budget office cost estimate S. 1932 Deficit Reduction Act of 2005. Retrieved July 23, 2007 from www.cbo.gov/ftpdocs/70xx/doc7028/s1932conf.pdf

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March 25, 2013

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Dear Ms. Kipson and Ms. Miron:

On behalf of the 1300 orthopaedic surgeons in practice in New York State, I would like to take this opportunity to provide preliminary comments to you regarding the February 25, 2013 letter to health care providers which was sent as a follow-up to the Report of Certificate of Need (CON) Redesign and Health Planning. The New York State Society of Orthopaedic Surgeons has significant concerns regarding a number of the provisions. Although these comments are prepared to address some of the issues raised, NYSSOS respectfully requests additional time to gather additional data and information to submit to you as a follow-up to this correspondence.

Preliminary information NYSSOS would like to draw your attention to includes information concerning the role of physician in-office imaging services. Page one of the letter state suggests that physician in-office imaging services result in increased healthcare expenses "including costs attributable to excess utilization due to self-referral patterns." This statement does not reflect the current literature regarding referral

patterns. Specifically, a study analyzing the impact of the self-referral ban instituted in the State of Maryland in 2010 has recently been concluded. The study examined the imaging studies ordered by the same two large orthopaedic practices for the same number of patients both pre and post implementation of the self-referral ban in that state. The report "showed that the there was no change in the ordering patterns of MRI's before and after the implementation of the self-referral ban and that the lag time [for patients to receive imaging studies that were ordered as part their medical treatment] ultimately increased [from an average wait time of 2 days to an average wait time of 4 days]." The study was just concluded and is pending publication in The Journal of Bone and Joint Surgery. I have enclosed a copy of the study here for your review and information.

In the original Report of the Public Health Planning Council on Redesigning Certificate of Need and Health Planning, Recommendation 8 expressed concern for the increased use of medical technologies and services and Recommendation 13 suggested that the criteria for imaging services in physician offices should be reviewed. There two elements of the report, which were included in the February 25th letter, have a lot of implications for the day-to-day operation of physician practices in NY and, if changed, will be very disruptive to patient care.

Evidence that cites increases in the number of physicians who self-refer patients for imaging does not account for the increase in self-referrals specifically applicable the providers who moved from the category of providers who do not self-refer to the category of providers who do self-refer. This shift is due to changes in practice patterns and a trend toward group practice developments. As physicians migrate to these types of practice settings in New York, patient imaging studies can be expedited with onsite imaging services.

It is also important to note that imaging studies that contain negative results for patients are an effective use of health care resources because they rule out surgical treatment options at an early point in the diagnosis of patient maladies. Negative imaging results are frequently reported in studies and being "unnecessary" because they do not reveal a significant health complications present in the patient. However, resources spent on imaging that are used to rule out serious complications result in the faster administration of appropriate treatment options.

Advances in medicine have resulted in more injuries and diseases being discoverable through imaging studies as the technology has improved. For example, MRI is the most accurate means by which to assess AVN, occult fracture in native hips. It is recommended by the FDA for assessment of ALTR around implants and it has been demonstrated to be the most accurate means by which to assess component loosening. New advances in imaging also enhance the ability to accurately assess articular cartilage which continually drives disease management (ie: "R/O meniscal tear" is often a chondral shear, requiring cartilage restoration techniques that have a markedly different rehab than simple meniscectomy). Additionally, many patients referred for "R/O labral tear" are found to actually have sacroiliitis and delays in imaging substantially delays institution of appropriate treatment for the inflammatory condition, sometimes with devastating results.

Medical science requires a commitment from physicians and patients to continue to work on advancing studies. Oftentimes these advances require the use of imaging studies. Any restriction that may be imposed by the State of New York on imaging services will have a chilling effect on medical advances.

Thank you for your review and consideration of these comments. As indicated above, NYSSOS would like to provide you with follow-up information as soon as it is prepared for distribution. The evolving science concerning these issues continues to generate more information and studies that inform the policies proposed for adoption.

Very truly yours,

Michael L. Parks, MD
President

Abstract:

Background: Magnetic Resonance Imaging (MRI) has become a routine test in the evaluation of musculoskeletal problems. Given the high utility of MRIs, many orthopaedic practices have purchased MRI machines for use in their own facilities. The State of Maryland viewed this practice as self-referral and banned it in January 2011. The purpose of this study is to assess the impact of the legislation on the MRI ordering patterns of orthopaedic surgeons. We analyzed medical records of separate patient encounters both before and after the self-referral ban. Our hypothesis is that this ban will have no significant effect on the number of tests ordered and will cause a delay in diagnosis.

Methods: We performed a retrospective chart review analysis of 3600 patient encounters of two large practices in Maryland. This included1800 patient encounters pre-ban and 1800 patient encounters post-ban for comparison. The primary measure was the percentage of MRIs ordered per patient encounter. We also examined the time from when the test was ordered to when it was performed in both groups.

Results: In 3600 patients, 1800 pre and 1800 post the percentage of MRIs decreased from 9.89% (178/1800) to 8.83% (159/1800), decreasing by 1.06% (95% CI -0.89% to +3.0%) which was not a statistically significant change ($p=0.28$). The time between request and service increased significantly ($p<0.001$; Mann-Whitney test) from a median of 2 days (25^{th} to 75^{th} percentile: 0 to 5 days) to 4 days (25^{th} to 75^{th} percentile: 1 to 9 days). The delay was significantly higher and more spread out post-ban, although the data was skewed upwards in both groups.

Conclusions: We showed that there was no change in the ordering patterns of MRIs before and after the implementation of the self-referral ban and that the lag time ultimately increased. We hope that this data will help to elucidate the MRI ordering patterns of orthopaedic surgeons as well as provide for well-informed evaluation of the impact of this legislation.

Level of Evidence: Level III

Introduction:

Magnetic Resonance Imaging (MRI) has been used for decades in the diagnosis of orthopaedic related disease. It is a frequently used in evaluating both soft tissue and osseous defects and the results of the scan are frequently used for treatment and operative planning. Given the high utility of the MRI scan, many orthopaedic groups across the country have started to purchase or lease MRI scanners for the group's use[1].

This has created some controversy, as many claim self-referral has led to more and, perhaps, unnecessary tests. Kalini et. al. looked at cardiac disease, orthopedics, rheumatology, and headache found that physicians who self-referred conducted more than twice the number of imaging tests compared with physicians who referred such imaging to a radiologist[5]. Using Medicare data from 1998, Baker et. al. looked at 1.1 million episodes of care with 11,844 orthopaedic surgeons showed that orthopaedists were referring for MRIs at a rate of 74 per 1000 episodes of care[6]. Previous publications have suggested that as many as 20%–50% of imaging procedures fail to provide information that improves patient welfare and therefore may represent, at least in part, unnecessary imaging service[7,8]. These statistics, however, do not consider the value of negative imaging results in influencing patient treatment and management[9].

Referring a patient to an MRI owned by the practice poses various clinical benefits as well as drawbacks. For example, proponents argue that this is convenient to patients and physicians and maintain that certain problems should receive imaging and treatment at a single office[10,11]. Furthermore, this allows for better access and more complete patient care as scans and plain radiographs are stored on the same PACS system and can be readily referenced by the provider. The most notable concern is that inherent conflicts of interest spur increased utilization of health care services generating excessive costs[12,13].

Recent attention has been shifted to the State of Maryland, once the number two prescriber of MRI scans per capita. In January 2011, Maryland State's highest court ruled that Maryland's self-referral law prohibits orthopaedists from ordering MRI scans for patients on their own machines[14].

We hypothesized that the self-referral ban would not result in a significant change in MRI ordering behavior, and the ban would increase the time from when the imaging was ordered to when it was performed. The number of MRIs which resulted in positive tests was also examined. Looking specifically at the number of MRI tests ordered in total and lead time from when the test was ordered to when it was performed, we analyzed two equal groups of 1800 patients from large orthopaedic practices in Maryland that owned their own MRI machine prior to this ban.

Materials and Methods:

This study targeted patients of attending orthopaedic surgeons in large group practices that owned and operated a MRI machine prior to this ruling. The total number of patients enrolled was determined by power analysis. Inclusion criteria for this study were patients seen as outpatients by attending orthopaedic surgeons who practiced primarily in the State of Maryland between January 1, 2010 and December 31, 2011. The ordering physicians must be in good standing with the state licensure board. Participating physicians will also have ordered MRIs for their patients during the year prior to the ban.

After appropriate IRB approval was obtained, the study was performed by reviewing 3600 outpatient records of orthopaedic patient encounters in the state of Maryland both pre-ban and post-ban. Patient encounters of large group practices were separated into two separate groups of 1800 outpatient encounters. The control group consisted of the first 1800 patients meeting the inclusion criteria in the time frame pre-ban. The encounters were examined chronologically and once 1800 patients had been analyzed, data collection ceased for that group.

As each patient encounter was examined we noted whether or not an MRI was ordered for that patient during the encounter. This allowed us to determine a percentage of MRIs ordered per patient visit. If an MRI had been ordered, we then determined when the MRI was actually performed. The same data was collected for the experimental group, which included patients after the ban. Each patient record was de-identified at the time of data collection prior to analysis.

The primary measure was whether an MRI was ordered during either a new patient or follow-up visit. Secondarily we examined if the ban decreased patient access and increased the time to diagnosis by examining the time it took for the MRI to be performed after it had been ordered both pre and post ban. Finally, we looked at whether the test had been interpreted as a positive result by the reading radiologist.

Results:

We examined 3600 separate patient encounters of large group practices in the Commonwealth of Maryland. In the pre-ban group of 1800, 178 patients had an MRI ordered at the time of the encounter (9.89%). The post-ban group had 159 MRIs ordered (8.83%). This 1.06% difference was not a statistically significant change (95% CI -0.89% to +3.0% p=0.28).

The time between request and service increased significantly ($p<0.001$;) from a median of 2 days (25^{th} to 75^{th} percentile: 0 to 5 days) to 4 days (25^{th} to 75^{th} percentile: 1 to 9 days). However, distribution of times was not-normally distributed and skewed upward for both groups.

The legislative ban on MRI did not affect the rate at which MRI findings were negative or positive. Our analysis showed that MRIs were negative in 13 of 178 exams pre and 5 of 159 post which was not statistically significantly different (p=0.15).

Discussion:

The purpose of this study was to evaluate the MRI ordering pattern both before and after the self-referral ban installed by Maryland legislation in January 2011 that prevented orthopaedic surgeons from ordering MRIs on their own machines.

It is important to address the underlying issue of the overutilization of diagnostic imaging in the healthcare system. Although reducing the use of diagnostic imaging may curtail the losses to insurance companies and cut overall healthcare spending, underutilization poses a very real and significant threat to patients and may lead to a negative impact on outcomes[15]. This study appraised the impact of prohibiting the self-referral behavior; however, access to diagnostic imaging in outside facilities is maintained. The legislation allows for a unique opportunity to study the effect of the ban on physician judgment and clinical decision making.

Our study embraces the unique opportunity to utilize the legislation to ban self-referral, as we retrospectively look at the MRI ordering patterns of the same orthopaedic surgeons, which is a novel approach to studying self-referral behavior.

The Medicare Payment Advisory Commission (MEDPAC) to Congress reports that the utilization of diagnostic imaging is growing more rapidly than that of any other type of physician service. The MEDPAC report insists that the true issue is not self-referral in and of itself but the fee-for-service system (FFS) that fuels higher volume self-referral of ancillary services[16]. Studies over the past 30 years have shown that non-radiologist physicians that utilize their own radiological equipment and self-refer have substantially higher utilization than physicians who refer to radiologists[17].

Prior to the self-referral ban, physicians in these practices were ordering at a rate of 9.89% and this decreased insignificantly to 8.83% after the installment of the ban. This data, although modest in its generalizability, disagrees with past studies comparing self-referring and non-self-referring physicians. The design of this study allows us to eliminate the variation in the baseline ordering patterns, for we compare the same physicians in the two different situations.

The lead time measures the time from the request for an MRI to the time that the MRI is performed. While in both groups the data was skewed upwards, the lead time increased significantly from a median of 2 days to 4 days. The increase in lead time may impact the quality of life and psychological burden of the patient as well as increase the risk of missing an emergent finding. The increased lead-time also increases the time to follow-up and may lead to decrease in the access to therapeutic measures. This study also could not evaluate the time and resources needed to obtain the MRI results post ban. When MRI's are obtained at an outside facility the results are not as readily available for the orthopaedist to review and the actual images not available for evaluation which can further delay treatment.

Our data suggests that the high volume of MRI ordering is not strictly due to self-referral, but represents a greater underlying behavior of physicians fueled by defensive medicine and the fee-for-service payment system[18]. Furthermore, the lack of any significant change despite the ban may imply a certain ingrained reliance on this specific imaging modality. Tort reform maybe the only way to reduce the number of MRI's ordered.

The impact of this legislation and the possibility to expanding it must be considered. Our data show that the legislation not only failed to decrease the number of MRI scans ordered but also significantly decreased patient access to an essential imaging modality. While the results may not seem so dramatic in a densely populated state such as Maryland, it can reasonably be inferred that in more rural areas with less physicians and healthcare infrastructure that this would have a more substantial impact in decreasing the patient's access.

The argument can also be made that radiologists, due to their training, are more adept at interpreting the radiographs. Many studies, however, have pointed out the fallacy in this, and orthopaedic surgeons have demonstrated equivalent if not greater accuracy in the interpretation of musculoskeletal studies[20].

This study had certain limitations that should be discussed. The study evaluated two large orthopaedic practices in Maryland, potentially leading to selection bias when extrapolating the data to the rest of the Maryland orthopaedic practices. It is possible that there would be differences in data if we included a larger number of patients and additional practices; however, the study offers a preliminary look into the ordering patterns of orthopaedic surgeons practicing in Maryland.

We hope that this study will elucidate the MRI ordering patterns of orthopaedic surgeons, and provide for a more well-informed evaluation of the Maryland self-referral legislation as the healthcare reform debate rattles on nationwide.

References

4. Levin, D. C., Rao, V. M., Parker, L., Frangos, A. J., and Sunshine, J. H. (2008). Ownership or leasing of MRI facilities by nonradiologist physicians is a rapidly growing trend. Journal of the American College of Radiology : JACR 5, 105-109.

5. Kilani, R. K., Paxton, B. E., Stinnett, S. S., Barnhart, H. X., Bindal, V., and Lungren, M. P. (2011). Self-referral in medical imaging: a meta-analysis of the literature. Journal of the American College of Radiology : JACR 8, 469-476.

6. Baker, L. C., Bundorf, M. K., and Kessler, D. P. (2010). HMO coverage reduces variations in the use of health care among patients under age sixty-five. Health Aff (Millwood) 29, 2068-2074.

7. Angrisano C, Farrell D, Kocher B, Laboissiere M, Parker S. Accounting for the cost of health care in the United States, January 2007. McKinsey Global Institute Web site. http://www.cows.org/healthcarecharrette/McKinsey-Healthcare.pdf.

8. Picano, E. (2004). Sustainability of medical imaging. BMJ 328, 578-580.

9. Hendee, W. R., Becker, G. J., Borgstede, J. P., Bosma, J., Casarella, W. J., Erickson, B. A., Maynard, C. D., Thrall, J. H., and Wallner, P. E. (2010). Addressing overutilization in medical imaging. Radiology 257, 240-245.

10. Varipapa, R. J. (1993). Physicians and outpatient diagnostic imaging: overexposed? JAMA : the Journal of the American Medical Association 269, 1633-1634.

11. Clark R, Anderson MB, Johnson BH, Moore DE,Herbert FD. Clinical Value of Radiologists' Interpretations of Perioperative Radiographs of Orthopedic Patients. Orthopedics 1996;19:1003–1007.

12. McDowell, T. N., Jr. (1989). Physician self referral arrangements: legitimate business or unethical "entrepreneurialism". American journal of law & medicine 15, 61-109.

13. Relman, A. S. (1985). Dealing with conflicts of interest. The New England journal of medicine 313, 749-751.

14. "State High Court Upholds Board Declaration Prohibiting Referrals Under Maryland Statute" BNA's Health Law Reporter, Vol. 20, February 3, 2011.

15. Otero H.J., Ondategui-Parra S., Nathanson E.M., Erturk S.M., Ros P.R. Utilization Management in Radiology: Basic Concepts and Applications (2006) JACR Journal of the American College of Radiology, 3 (5) , pp. 351-357

16. Medicare Payment Advisory Commission. 2011a. Report to the Congress: Medicare payment policy. Washington, DC: MedPAC.

17. Levin, D. C., and Rao, V. M. (2004). Turf wars in radiology: the overutilization of imaging resulting from self-referral. Journal of the American College of Radiology : JACR 1, 169-172.

18. Sethi, M. K., Obremskey, W. T., Natividad, H., Mir, H. R., and Jahangir, A. A. (2012). Incidence and costs of defensive medicine among orthopedic surgeons in the United States: a national survey study. Am J Orthop (Belle Mead NJ) 41, 69-73.

19. Kim, A., Khoury, L., Schweitzer, M., Jazrawi, L., Ishak, C., Meislin, R., Kummer, F., and Sherman, O. H. (2008). Effect of specialty and experience on the interpretation of knee MRI scans. Bulletin of the NYU hospital for joint diseases 66, 272-275.

20. Nayak, K. N., Rorabeck, C. H., Bourne, R. B., Mulliken, B., and Robinson, E. (1996). Interpretation by radiologists of orthopedic total joint radiographs: is it necessary or cost-effective? Canadian journal of surgery Journal canadien de chirurgie 39, 393-396.

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Dear Ms. Lipson and Ms. Miron:

Thank you for the opportunity to provide comments to your letter of February 25, 2013. As leaders of large physician practices located in Westchester, Putnam, Dutchess, and Ulster Counties, we are interested in New York State Department of Health's (NYSDOH's) review of the facility licensure requirements and the certificate of need process. Because of our common interest in this issue, we are writing this letter together to briefly provide our comments. We look forward to a continuing dialogue on this important issue.

All of our practices provide high quality, coordinated, cost effective care across a wide range of medical specialties, including ancillary services (laboratory and diagnostic imaging), urgent care and office based surgery. Some of our practices also operate ambulatory surgery centers licensed under Article 28 of the New York State Public Health Law and provide radiation therapy. All of our practices serve Medicaid patients through the Medicaid fee-for-service program, Medicaid managed care contracts, or both.

Updating the Certificate of Need (CON) Process

The 2011 CON reforms reduced the number of projects that are subject to CON review. We applaud the Department's continued evaluation of the CON processs and hereby suggest that the CON process should remain intact only for construction of new hospital facilities. The CON process no longer serves its original purpose of controlling costs, as New York State's regulated rate system no longer exists. Rather, the CON process often serves to increase costs. Article 28 facilities receive higher rates of reimbursement (due to the facility fee) when they provide the same service as non-Article 28 providers. Furthermore, as discussed below, the CON process is not always an effective way, nor the only effective way, to assure quality and patient safety.

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With the implementation of the Patient Protection and Affordable Care Act and the expectation that an increasing number of insured patients will be seeking health care services, physicians and other providers will need to respond to market forces in a quick and pro-competitive manner. Even with recent steps taken by NYSDOH to streamline the CON process, the expense and time involved in obtaining CON approval does not foster the flexibility and innovation necessary to succeed in the rapidly changing health care environment. The CON process also discourages capital investment, as potential investors may understandably hesitate to commit their capital to projects if they are uncertain as to their eventual approval.

With regard to urgent care, office-based surgery, advanced imaging and radiation therapy provided by physician practices, we believe that the current system of regulation (e.g., radiation safety, incident reporting) without a CON process is adequate to assure safety and quality while also ensuring access to care, cost containment, and promoting physicians' ability to coordinate patient care and improve population health in the community. Larger physician practices such as ours are more likely to have established care coordination and quality and utilization review systems to ensure the "triple aims" of the right care, at the right place, at the right cost.

The criteria found in 10 NYCRR § 600.8 and court decisions that have attempted to distinguish between a physician practice and an institutional provider of health services that must have Article 28 licensure are no longer reflective of the current care delivery model we represent. Many of the factors cited in the regulation (e.g., centralized business and ancillary services, adherence to standards of the practice, medical records maintained by the practice, a large physical structure, and methods of distributing income among members of the practice) have become hallmarks of successful physician practices. These factors are no longer appropriate indicia of a need for licensure or a trigger of the CON process.

Quality, Efficiency and Cost Savings

Our practices provide quality care. We know this by virtue of the third party and voluntary governmental certifications our practices have obtained. These certifications vary by practice, but they include NCQA accreditation and patient-centered medical home recognition, AAAASF certification, AAAHC accreditation, and certification as accountable care organizations in the Medicare Shared Savings Program. Our practices also participate in the CMS Physician Quality Reporting System. In connection with these certifications and programs, our practices are required to submit data by which the quality of care is measured on a regular basis.

All of our practices employ Electronic Medical Record (EMR) systems, resulting in better coordination of care, fewer medical errors and easy access to quality of care and utilization data. Patient portals permit our patients to communicate easily with their physicians, resulting in patients taking a more active role in their health care. Our large practices result in lower costs to

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the health care system, as we achieve economies of scale by consolidating our purchasing, billing, human resources, information technology and other services. Our primary care practitioners' focus on preventive care and coordination of specialty care also results in lower costs to the health care system.

Our practices adopted and implemented all of these systems and processes in the absence of any regulations requiring us to do so. In its letter to providers, NYSDOH recognizes that this type of robust administrative infrastructure can support new models of care and payment, which allow physician practices to implement evidence-based medicine and promote population health. Consistent with the goals of the Patient Protection and Affordable Care Act, our practices are able to tailor our systems and processes to effectively coordinate care among providers and improve our patients' health. We believe that voluntary third-party certifications and accreditations are not only an effective method, but the best method, for assuring and continuously improving the quality and safety of care provided by physician practices.

Safety Net Providers

We understand that NYSDOH is concerned about disparities in care with regard to the Medicaid and uninsured populations. Our physician practices all provide care to the uninsured at rates that are far below our commercial fees. Most of our practices provide "urgent care," through offices open on nights and weekends, which are open to patients of our practices as well as new patients. All of our practices also participate in Medicaid managed care. However, there is currently no effective payment mechanism in New York State for Medicaid patients and the uninsured to receive the full range of high quality, cost effective, coordinated care across all practice settings. We believe there are potential advantages to an expansion of Medicaid risk contracting, but suggest this must be done in concert with an effective gatekeeper to ensure proper care coordination and cost containment. Using the CON process to force a solution to the problem of disparity of care would be costly and probably would not be effective. Accordingly, our practices would welcome the opportunity to engage in a public dialogue on how to reduce or eliminate disparities in care for Medicaid patients and the uninsured while providing the highest quality care that our patients deserve.

Thank you for the opportunity to provide our comments. We look forward to a continuing discussion with you.

Sincerely,

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March 22, 2013

New York State Public Health and Health Planning Council
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On behalf of the New York Chapter of the American College of Physicians (NYACP) and its 12,000 physician specialists in Internal Medicine who provide medical care to the State's adult population, we wish to offer comment on the PHHPC recommendations regarding the growing market presence of "single and multi-specialty mega physician practices" and other emerging healthcare entities.

We sincerely appreciate being asked for such comments in your February 25, 2013 communication, and we have studied closely the series of questions you pose. While we will not comment on each of them individually, we hope that our statements will help to inform your deliberative process and convey a sense of caution as you proceed with consideration of extending the CON process in new and untested ways. We have added our name to a much more detailed letter being submitted by numerous stakeholders, including MSSNY and many other specialty societies.

First and foremost, let us emphasize our shared vision and goal for improving the quality of healthcare and improving access to such care for all. The American College of Physicians, nationally, and the NYACP here in New York, have long been advocates for patient safety and quality improvement, and have led the profession in setting practice expectations and standards. With more citizens receiving coverage under New York's developing health benefits exchange, we share and support the IHI Triple Aim, and commend the PHHPC for keeping this paradigm as a goal for improvement in the healthcare system. We also believe that quality standards and measures, as established by the physician specialty organizations and medical boards, must be expanded and implemented within ambulatory care practices as well as other facilities. Much can be done to define and promulgate best practices, and we continue to work toward adoption of clinical outcomes that are meaningful, actionable and measurable.

Before addressing the recommendations in your letter (which appear to be related to recommendation #13 of your 23 recommendations), we would like to address recommendation #6. Recommendation #6 suggests elimination of CON for primary care facilities, whether DT & Cs or hospital extension clinics, and retention of licensure requirements. We would expect that

Recommendation #6 should also apply to private primary care practices – as the need for more primary care is urgent regardless of service delivery site or governance structure. Primary healthcare continues to experience shortages which are predicted to become worse as the need for primary care increases. Therefore, the recommendation to eliminate CON should be extended to all primary care regardless of practice arrangement or site.

With regard to the questions you specifically posed to the stakeholders, we would begin by inquiring about the efficacy, validity and impact of New York's CON process as a whole. Since CON was implemented in New York decades ago when the healthcare system operated in a very different way, we would ask the PHHPC to entertain a carefully constructed evidence-based study to evaluate the impact of CON to date on cost, efficiency and quality of care. Prior to any recommendation of expansion, such study is necessary to provide a basis for knowledgeable decision-making.

If, after careful study and analysis of data, it is determined that CON has been a productive process that has enhanced efficiency and quality, and is still a process that applies to the current healthcare environment within New York, then, any current practice should be "grandfathered" for its current facilities and equipment. If the studies show that new CON requirements should be applied, it should only apply to new endeavors to prevent serious disruption of existing healthcare services.

We are quite concerned with the issue of "ownership interest" as this is a multi-faceted issue. The corporate practice of medicine has long been clearly defined and, in some instances, prohibited by New York statute, and current attempts to re-align this definition to fit emerging models of care require careful study. With specific reference to "retail" or "limited service" clinics, we suggest that publicly-traded corporations which operate to provide increased returns to their stockholders require a different set of rules than privately-owned professional corporations already subject to New York State corporate practice of medicine rules and self-referral restrictions. Demonstration of need, quality, facility structure and compliance must be required for "limited service" sites.

Restrictions of inherent "ownership" relationships and "self-referral to ancillary services" must also be addressed. New York has a long history of imposing restrictions on private practices, and they should be applied to emerging healthcare delivery models as well.

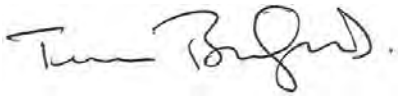
We also would state that any use of public funds such as bad debt and charity care, HCRA, or any other form of public financing should require enhanced scrutiny through rules and regulation. Utilization of taxpayer dollars to support establishment or expansion of facilities is different from private funding or support. Use of public funds demands increased scrutiny for care quality and cost efficiency.

We are confused by the term "mega-practices" as used in the stakeholder letter. Does this mean a certain number of physicians within a practice, a minimum or maximum number of related practices, practices that are strictly ambulatory care or those having relationships with health centers or hospitals? Coming at a time when public policy has encouraged practices to align with one another to achieve cost efficiency, explore new reimbursement methodologies and to

move toward multi-disciplinary teams to deliver more coordinated care, this seems to be a conflicting policy approach.

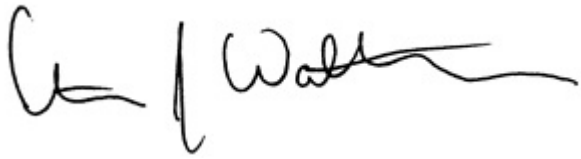
In conclusion, we suggest that the PHHPC must demonstrate evidence-based decision-making with regard to regulatory changes in oversight of care, regardless of the setting where such care is delivered. Public safety and quality of care should be our first consideration.

Sincerely,



Terence Brady, MD, FACP
Chapter President and
Governor – Brooklyn/Queens/Staten Island Region

Andrew Dunn, MD, FACP
Governor – Bronx Manhattan Region



Steven Walerstein, MD, FACP
Governor – Long Island Region

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March 25, 2013

VIA E-MAIL: phhpcplanning@health.state.ny.us

Karen Lipson, Director
Division of Policy
Office of Health Systems Management
New York State Department of Health

Joan Cleary Miron, MPH, Director
Division of Primary Care Development
Office of Primary Care
New York State Department of Health

Dear Ms. Lipson and Ms. Miron:

The number of New York State citizens who seek "unscheduled care" for illness and injury has grown exponentially over the decades. Educated prudent layperson concerns, advancing emergency department quality and capability, diminished primary care capacity, and a growing number of urgent care facilities are among the several reasons for this trend.

All emergency physicians believe in high quality care. Accordingly, the New York American College of Emergency Physicians firmly believes that the people of New York deserve to know that the facility they approach for unscheduled care meets standards set forth by the New York State Department of Health. The standards should apply to emergency departments, stand alone emergency departments and urgent care centers. Appropriate standards should be applied to all practice environments that advertise or imply urgent or emergency care.

To our knowledge, only one state, Arizona, has an Urgent Care license requirement. Illinois, Delaware, and New Hampshire have placed restrictions on how Urgent Care Centers can be identified and marketed to the public. California, Ohio, Colorado, Iowa, Illinois, New York and New Jersey require physician ownership of Urgent Care Centers. New Jersey law defines and refers to urgent care as "ambulatory care" and the New Jersey Department of Health and Senior Services (DOHSS) regulate ambulatory care facilities in accordance with the mandates outlined in Chapter 31A of Title 8 of the New Jersey Administrative Code (NJAC).

A prudent layperson in New York State who is in need of unscheduled care for an injury or illness deserves to be fully informed and confident of the abilities and standards of the health care providers they seek out, whether it be in a hospital emergency department, a standalone emergency department or an urgent care center.

Sincerely,

Daniel G. Murphy, MD MBA FACEP
President

Urgent Care Association of America

Memo to: Karen Lipson, Director, Division of Policy
New York State Department of Health - Office of Health Systems Management

Joan Cleary Miron, MPH, Director, Division of Primary Care Development
New York State Department of Health - Office of Primary Care

From: Marc Salzberg, MD, FACEP
President, Urgent Care Association of America

Date: March 20, 2013

Thank you for inviting the Urgent Care Association of America (UCAOA) to respond to questions posed in the February 25, 2013 New York State Department of Health (DOH) letter. On behalf of the members of the UCAOA, we offer an overview of urgent care medicine in order to help inform the State's Public Health and Health Planning Council (PHHPC) regarding the perspective on Certificate of Need (CON) Redesign and the positive impact of urgent care centers and practice models on health care cost, quality and access in New York State.

Urgent care centers provide walk-in, extended hour access to adults and children for acute illness and injury care. Urgent care centers may also provide other healthcare services like sports and school physicals, travel medicine, and occupational medicine.

Patients should visit an urgent care when their condition is beyond the scope or availability of their regular primary care provider—or not severe enough to warrant a trip to the emergency room. Some of the most common conditions treated are fevers, upper respiratory infections, sprains and strains, lacerations, contusions, and back pain. Most centers also treat fractures, can provide IV fluids, and have x-ray and lab processing onsite.

Centers are typically staffed with physicians, and may also have physician assistants, nurses, nurse practitioners, medical assistants and radiology technicians working with patients. Patients are usually seen by a physician, nurse practitioner, or physician assistant in either 0-15 minutes or 15-45 minutes. Since no appointment is necessary wait time may vary.

Urgent care centers typically operate 7 days a week (including holidays), open between 8 and 9 am, and close between 7 and 9 pm on the weekdays. Hours may be somewhat earlier on the weekends.

The cost for treatment at an urgent care center ($185 inclusive of lab and x-ray) is usually comparable to a primary care visit $185 exclusive of lab and x-ray), and less than the emergency room ($922 exclusive of lab and x-ray). Charges vary according to individual insurance coverage. Most insurance plans are accepted at urgent care centers; however, insurance is not required.

Urgent care centers are usually located in freestanding buildings, and the majority of centers are independently owned by physicians or groups of physicians. Approximately 25 percent are owned by a hospital or health system – and most of those are located off the main hospital campus.

UCAOA recommends that all individuals have a primary care physician and supports the American Academy of Family Physician's concept of a "medical home." While some urgent care centers formally provide ongoing primary care, many centers do not and refer patients to a local physician group to serve as their primary care provider. Patients will be referred to a specialist for follow up as needed, and back to their regular physician for ongoing care. Centers may also refer patients to a primary care doctor if they don't already have one.

Urgent care centers are NOT freestanding emergency departments. They are not equipped to treat life-threatening emergencies, nor provide assistance for labor and delivery. Urgent care centers will refer patients to the emergency room if their condition is very serious.

Urgent care centers are NOT the same as in-store retail clinics. Urgent care centers treat a broader scope of services and ages (most retail clinics' minimum age is 18 months) than retail clinics, and have a different staffing model (primarily physicians vs. primarily NPs). Most retail clinics and urgent care centers in a community have a good referral relationship.

It is the position of UCAOA, that urgent care centers are no different than other primary care medical practices such as internal medicine and family practice and it is noted that these have never been subject to additional New York State DOH regulations or CON applications. The impact of urgent cares on patient care is positive and they are extremely cost effective and actually aid overburdened primary cares and emergency departments**.** It should also be noted that the average urgent care center employs 20-25 staff that might otherwise be unemployed.

Please feel free to contact us should you have any questions. I can be best reached through our national headquarters. Please contact Joanne Ray, Chief Executive Officer at jray@ucaoa.org [redacted].

March 25th, 2013

Karen Lipson
Director,Division of Policy
Office of Health Systems Management

Joan Cleary Miron, MPH
Director,Division of Primary Care Development
Office of Primary Care

NYS Department of Health
Empire State Plaza- Corning Tower
Albany, New York 12237

Dear Ms. Lipson and Miron,

The undersigned organizations wish to thank you for the opportunity to comment on the New York State Department of Health request for commentary regarding New York State's Public Health and Health Planning Council (PHHPC) recently released report on Certificate of Need (CON), in particular on the potential impact of regulatory changes on patients who suffer from urological disorders.

Introduction

It is the desire of both policy makers and health care providers to simultaneously ensure access to healthcare that is both high quality and cost effective. To that end, Federal regulations instituted in 1974 required that all states develop a CON process that required provider to obtain approval from a designated state agency before expansion of services would be permitted; this was particularly true of such services that required concentrated expertise or were particularly expensive. These regulations expired in 1986; continuation of such laws was left to the discretion of individual states. Presently, thirty-six states retain some form of CON regulation.

Literature suggests that by their very nature, CON laws serve as a barrier to competition in the delivery of health care services.[1,2] By providing artificial regulation of the market, the regulations protect incumbents against competition from new providers and may provide an

[1] Burda D. CONspiracies to crush competition. Hospitals using CON laws to thwart rival's projects. Mod Healthc. 1991 Jul 8;21(27):28-30, 32-4, 36.
[2] Eichmann TL, Santerre RE. "Do hospital chief executive officers extract rents from Certificate of Need laws?." Journal of Health Care Finance 37.4 (2011): 1.

impediment to the effective delivery of healthcare under new payment paradigms that are mandated by the Patient Protection and Affordable Care Act (PPACA). It is goal of integrated urology groups to deliver a community based alternative to inefficient, impersonal and high cost institutional based care, thereby improving access, enhancing outcomes and reducing costs. We support the position of the Medical Society of the State of New York (MSSNY) that CON process as presently exists in the State of New York should be repealed or significantly revised so as to promote innovative and cost efficient practice models in this state. We agree with MSSNY that New York State should not expand or modify the criteria that define a diagnostic and treatment center under 10 NYCRR 600.8 to encompass any additional physician practice models.

Responders

The signatories to this letter represent both state and national organizations that are committed to the delivery of high quality urologic services in the site of service of the patient's choosing.

About the New York Section of the American Urological Association (NYAUA)

The NYAUA has 917 physician members practicing in the southeastern portion of the state of New York, including Long Island and the northern portion of the state of New Jersey. The NYAUA is proud to host 15 outstanding urological residency programs, which are currently training over 130 Residents and Fellows in urology. Every year the NYAUA successfully organizes more educational meetings than any other Section of the AUA. Its mission is to promote the highest standards of urological clinical care through education, research and in the formulation of health care policy.

About the New York State Urological Society (NYSUS)

The New York State Urological Society, NYSUS, is a specialty medical society comprised of Urologists in New York State who are dedicated to the continual improvement of clinical care, patient satisfaction and patient access through education and cohesive action of its members.

The mission of the Society shall be to study and evaluate the economic aspects of the specialty of urology and to represent the Urologists of New York State at all levels of government and for all socioeconomic matters required thus promoting the ethical practice of Urology in the best interests of the public and medical profession with continual improvement of professional standards. In addition, the mission will include advising concerned professional groups regarding matters related to Urology.

About the New York Urology Trade Association (NYUTA)

NYUTA was organized to promote and represent the common business interests of and improve the business conditions among individuals and other business entities engaged in medical practices specializing in the provision of urological medical services and other allied healthcare entities. Its goals are to further the corporation's members who are engaged in the medical profession of urology by promoting friendly discourse among the corporation's members and other allied healthcare entities as well as to promote certainty within the medical profession of urology, and to promote and maintain high standards of excellence among urology practices and

other allied healthcare entities. To this end the organization is committed to assisting others in developing and implementing public policy affecting urology practices at the state and federal levels, through legislation and regulation.

About the American Urological Association

Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association is a leading advocate for the specialty of urology, and has more than 19,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

About the American Association of Clinical Urologists (AACU)

The AACU is the only national organization to serve urology with the sole purpose of promoting and preserving the professional autonomy and financial viability of each of its members. AACU's resources are dedicated to inform members of the issues affecting their practice and profession, and then to work directly to influence the resolutions of these issues. Forty-five percent of all urologists nationwide are members of the AACU.

About the Large Urology Group Practice Association (LUGPA)

LUGPA represents 115 large urology group practices in the United States, with more than 2,000 physicians who make up more than 20 percent of the nation's practicing urologists. LUGPA's vision is to be the premier organization of group practices committed to the delivery of high quality and efficient comprehensive urological care. Its mission is to provide urological surgeons practicing within the context of large group practices the means to access resources, technology and management tools that will enable them to provide all services needed to care for the patients with acute and chronic illnesses of the genitourinary system in an efficient, cost effective and clinically superior manner, while using data collection to create parameters that demonstrates quality and value to patients, vendors, third party payors and regulatory agencies.

The Development of Integrated Urology Care

The changing medical-economic environment has created numerous challenges for physicians in private practice, many of whom balance patient care with administrative responsibilities. An increasingly complex regulatory environment has led many physicians to abandon independent medical practices and seek employment with hospitals or other entities.[3,4] An alternative strategy for physicians who value independent practice is consolidation of practices into single- or multi-specialty groups. By incorporating efficiencies of scale, these groups may afford physicians the opportunity to retain the characteristics of traditional medical practices, while improving their ability to adapt to changing healthcare circumstances.[5] These groups often provide other services, including laboratory tests, diagnostic imaging, and radiation therapy. Proponents of

[3] Isaacs SL, Jellinek PS, Ray WL. The independent physician--going, going…. N Engl J Med. 2009;360(7):655-657

[4] Elliott VS. Hospitals seek best ways to achieve physician alignment [Internet]. Amednews.com; 2010[cited 2010 Apr 12]. Available from: http://www.ama-assn.org/amednews/2010/04/12/bisc0412.htm.

[5] Greaney TL. Managed competition, integrated delivery systems and antitrust. Cornell Law Rev. 1994;79(6):1507-1545.

these arrangements argue that integration of medical services facilitates the development of coordinated clinical pathways, improves communication between specialists, offers better quality control of ancillary services, and enhances data collection, all of which can improve patient care and lead to lower costs.[6,7,8] Indeed, recent literature confirms that single specialty pathology laboratories operated by urologic practices enjoy lower rates of certain specimen processing errors in prostate biopsies than either commercial or hospital based laboratories.[9]

Integration of Services into Urology Groups Improves Access, Does not Increase Utilization and Does not Impede Competition: the Example of Radiation Oncology

Perhaps no type of integrated health care services has engendered more controversy than the incorporation of advanced radiation oncology services into the comprehensive urology group practice settings. In the February 25th stakeholder commentary request letter, the DOH specifically references quality of such services provided in the physician office setting, also stating, "…health care facilities must be licensed and are subject to various regulations governing their operations and physical plant. Physician practices are not generally subject to these regulations."[10] Regarding radiation regulations, the following is excerpted from existing DOH regulations defining radiation facilities:

> "Radiation installation" means place, facility or mobile unit where radiation equipment, in operable condition or intended to be used, is located or used, or where radioactive material is transferred, received, possessed or used including generally a hospital; medical, dental, chiropractic, osteopathic, podiatric, or veterinarian institution, clinic or office; educational institution; commercial, private or research laboratory performing diagnostic procedures or handling equipment or material for medical use; or any trucking, storage, messenger or delivery service establishment. Radiation installation shall include, whether or not it is specifically stated above, any place, facility or mobile unit where radiation is applied intentionally to a human.[11]

It is important to note that this definition does not distinguish between hospital facilities and physicians' offices in regards to applicability of radiation regulations; in fact, physician's offices must comply with these policies.

With reference to quality of radiation services as delivered in the office vs. facility setting, a comprehensive review of the literature failed to reveal a single reference that illustrated any difference in outcomes based on site of service of radiation delivery. The most significant

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[6] Uzych L. Physician ownership-referral arrangements in the United States. Med Law. 1990;9(1):701-706

[7] McDowell TN Jr. Physician self referral arrangements: legitimate business or unethical "entrepreneurialism". Am J Law Med. 1989;15(1):61-109.

[8] Todd JS, Horan JK. Physician referral--the AMA view. JAMA. 1989;262(3):395-396.

[9] Pfeifer JD, Liu J. Rate of Occult Specimen Provenance Complications in Routine Clinical Practice. Am J Clin Pathol. 2013 Jan;139(1):93-100

[10] NY DOH Stakeholder Comment Request, February 25th, 2013

[11] 10 NYCRR Section 16.2(a)(98), revised April 18, 200. Accessed at: http://www.health.ny.gov/environmental/radiological/radon/radioactive_material_licensing/docs/part16.pdf

incidents of radiation safety issues in New York State have occurred in the hospital setting.[12] While these reports cannot be generalized to all hospitals, certainly no evidence supports the notion that quality of radiation services in the physician office setting is inferior to that at hospital facilities.

Given that the quality of radiation treatments are equivalent based on site of service, and that physicians' offices must meet rigorous DOH regulatory standards, those committed to restricting the ability of group practices to integrate radiation oncology have focused their arguments on alleging overuse of such technology. In reality, a critical review of utilization patterns for radiation oncology services illustrates the following:

1. Increased utilization of IMRT reflects a changing clinical standard from an older, more dangerous and less effective form of radiation treatment and is occurring in treating other disease states as well as prostate cancer;
2. The trend towards increased utilization of IMRT in the treatment of prostate cancer actually predated the formation of integrated urology groups, and this trend is similar regardless of whether the service is provided in the hospital or physician office setting;
3. Patients who received radiation treatment for prostate cancer at a physician's office were much more likely to receive state-of-the-art radiation when compared to patients treated at the hospital setting; and
4. Ownership of radiation oncology services by physicians does not impede hospitals' ability to compete in radiation services.

Utilization of IMRT Reflects a Changing Clinical Standard

Historically, the treatment option most commonly utilized by prostate cancer patients is known as external beam radiation therapy (EBRT). The advent of intensity modulated radiation therapy (IMRT), and subsequent addition of advanced targeting modalities such as image-guided radiation therapy (IGRT), allows for dose escalations in excess of 81 Gray (Gy) with minimal local toxicities;[13] the clinical superiority of these doses in managing localized prostate cancer over historical forms of EBRT (such as 3-dimensional conformal radiation therapy – 3DCRT) has been confirmed.[14] The preference of the older male for treatment that 1) can be performed on an outpatient basis; 2) is non-invasive; and 3) is both efficacious and safe was illustrated in a large study of over 85,000 Medicare beneficiaries, which found that when offered consultation by both a surgeon and non-surgeon, 83% of patients chose EBRT over radical prostatectomy.[15]

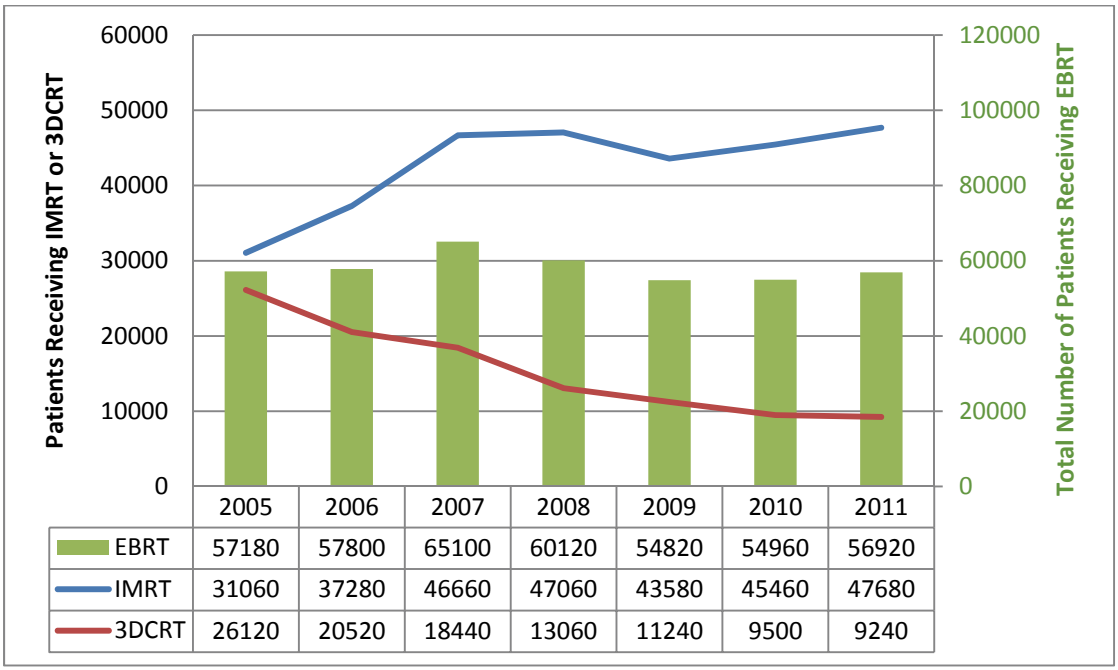
[12]Bogdanich, W. The Radiation Boom: Radiation Offers New Cures, and Ways to Do Harm. The New York Times, January 23, 2010.

[13]Zelefsky MJ, Fuks Z, Hunt M, et al. High-dose intensity modulated radiation therapy for prostate cancer: early toxicity and biochemical outcome in 772 patients. Int J Radiat Oncol Biol Phys. 2002 Aug 1;53(5):1111-6.

[14]Viani GA, Stefano EJ, Afonso SL. Higher-than-conventional radiation doses in localized prostate cancer treatment: a meta-analysis of randomized, controlled trials. Int J Radiat Oncol Biol Phys. 2009 Aug 1;74(5):1405-18.

[15]Jang TL, Bekelman JE, Liu Y, et al. Physician visits prior to treatment for clinically localized prostate cancer. Arch Intern Med. 2010;170(5):440-450.

That said, further review of the patterns of therapy within EBRT is revealing[16] :



	2005	2006	2007	2008	2009	2010	2011
EBRT	57180	57800	65100	60120	54820	54960	56920
IMRT	31060	37280	46660	47060	43580	45460	47680
3DCRT	26120	20520	18440	13060	11240	9500	9240

Figure 1: Use of External Beam Radiation to Treat PCa in Medicare Beneficiaries, 2005-11

This graph, representing the utilization of EBRT to treat prostate cancers in the Medicare population, reveals a very important trend, that is, that although absolute number of Medicare beneficiaries who received EBRT (note: plotted on secondary axis, demarcated in green) actually declined over the period 2005-2010, during this interval there was a marked shift from historical 3D-RT) towards IMRT. This data supports reports from a smaller subset of patients that by 2007, 77% of EBRT was via IMRT;[17] our analysis indicates that by 2011 this had increased to 84%. These trends have been demonstrated to virtually identical regardless of whether IMRT was delivered in the physician office or outpatient hospital setting.[18] The clinical superiority of IMRT over 3DCRT prompted the National Comprehensive Cancer Network (NCCN) to state in its 2010 guidelines that, "the second generation 3-D technique, intensity-modulated radiation therapy (IMRT), is now state-of-the-art and required."[19]

[16]Milliman, Inc. was retained to access and summarize the Medicare 5% sample data files for the years 2005-2011for CPT codes referable to prostate cancer treatment. This data was analyzed by LUGPA in accordance with accepted peer-reviewed methodology; any data so obtained will be referenced LUGPA.

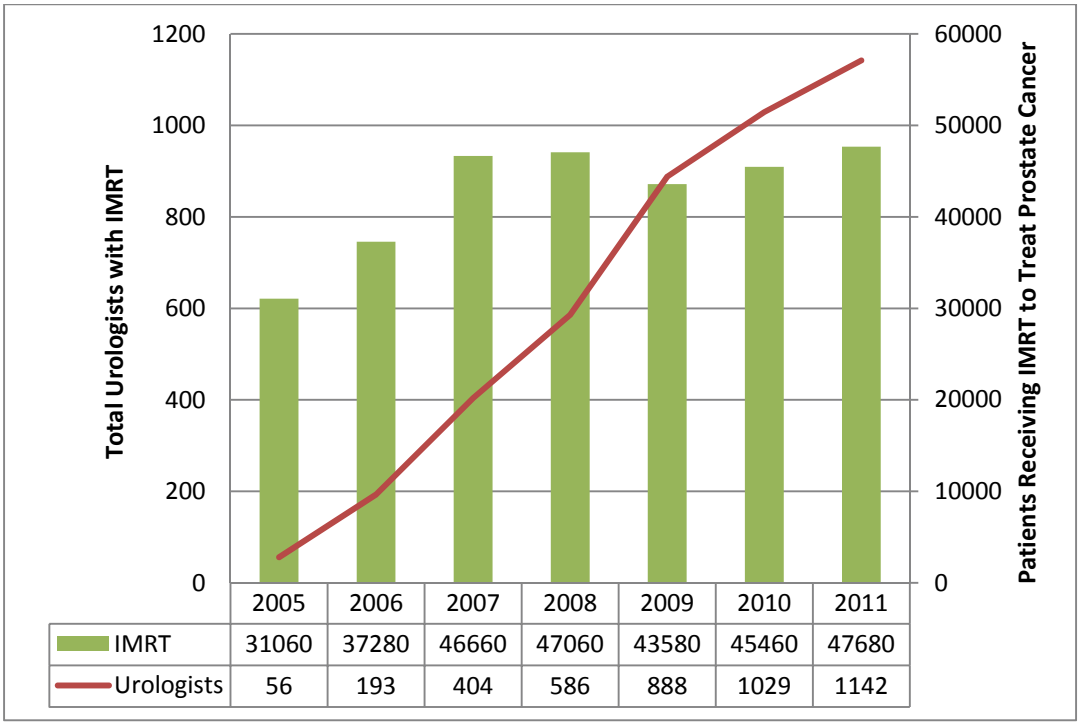
[17]Dinan MA, Robinson TJ, Zagar TM,et al. Changes in initial treatment for prostate cancer among Medicare beneficiaries, 1999-2007. Int J Radiat Oncol Biol Phys. 2012 Apr 1;82(5):e781-6.

[18]Kapoor DA, Zimberg SH, Ohrin LM, et al. Utilization trends in prostate cancer therapy. J Urol. 2011 Sep;186(3):860-4.

[19]Mohler J, Bahnson RR, Boston B, et al. NCCN clinical practice guidelines in oncology: prostate cancer. J Natl Compr Canc Netw. 2010;8:162-200.

Ownership of Radiation Oncology Services Does Not Correlate with Utilization

That urology ownership of IMRT equipment did not drive utilization of this is further illustrated by comparing the number of urologists practicing in groups with IMRT capability to the total number of patients receiving IMRT to treat prostate cancer:[20]



	2005	2006	2007	2008	2009	2010	2011
IMRT	31060	37280	46660	47060	43580	45460	47680
Urologists	56	193	404	586	888	1029	1142

Figure 2: IMRT to Treat Prostate Cancer in Medicare Beneficiaries vs. Urologists in Practices with IMRT, 2005-11

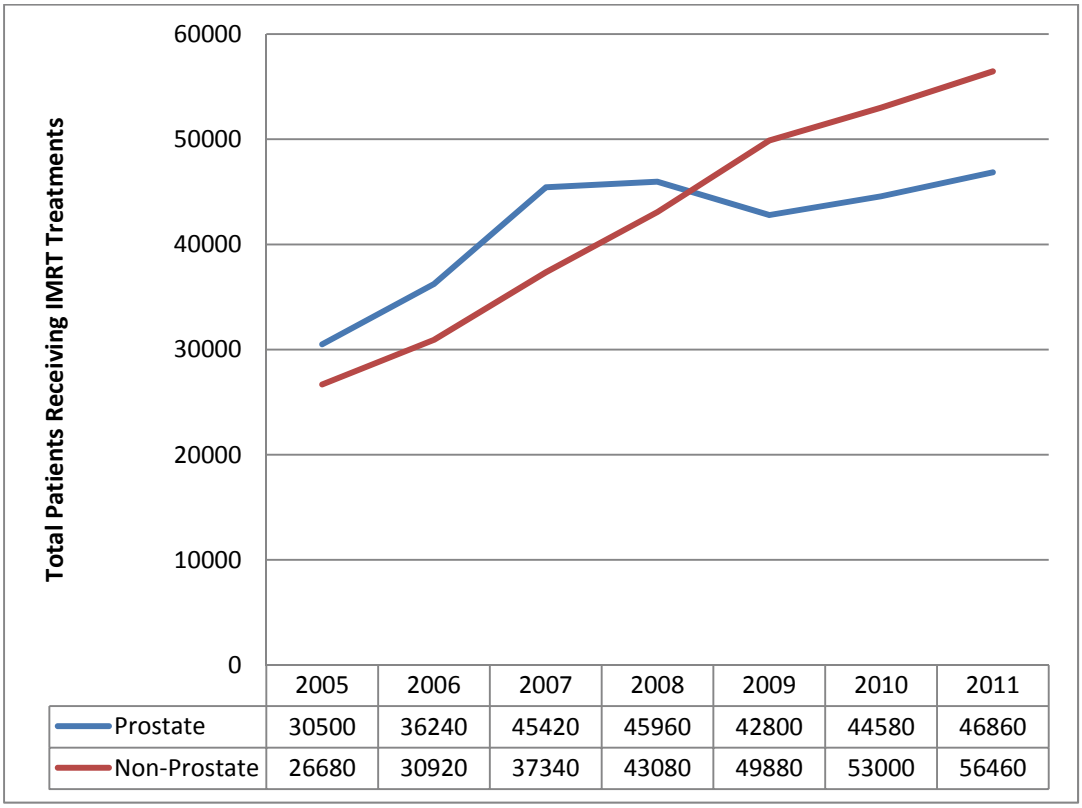
This reveals that although the greatest increase in IMRT utilization to treat prostate cancer occurred from the years 2005-07, by that time only a relatively small number of urologists had incorporated IMRT into their practices. From 2007-11 while the number of urologists whose practices incorporated IMRT increased from 404 to 1142 (182.7%), during that same interval, IMRT treatments increased by a mere 2.2%. Statistical analysis reveals that over this interval there is absolutely no correlation whatsoever between urology ownership of IMRT and the number of patients who received this treatment (r=-0.13).

These trends illustrate a significant error made by those that suggest urology ownership of IMRT is driving utilization of these services, that is, failure to account for the timing of ownership of such services relative to the increased utilization of these services. Given the absence of any substantive data supporting this claim, opponents of the integrated cancer care model have relied heavily on anecdotal data and editorial commentary to imply that coordinated cancer care leads to over-utilization of services. The most commonly referenced article critical of physician ownership of radiation facilities was published in the Wall Street Journal.[21] The WSJ reported that the utilization of IMRT in states with integrated urology groups (such as NY, NJ and FL) was much higher in 2008 than the national average. The WSJ further concluded from its

[20] Op. cit., LUGPA 2013.
[21] Carreyrou, J. "A Device to Kill Cancer, Lift Revenue." Wall Street Journal, December 8, 2010.

research that the presence of integrated urology groups in those states must have been responsible for the higher utilization of IMRT as compared to the rest of the country. The WSJ published a list of the integrated groups in the targeted states that, as of the time of publication of the article in December 2010, were delivering radiation. However, the WSJ did not report when these integrated urology groups started delivering these IMRT services. The clear implication from the article is that the integrated groups were furnishing the IMRT services during the time period studied by the WSJ. This is simply wrong. In fact, during the time period studied, only one urology practice in NY was delivering IMRT, only two urology practices were delivering IMRT in FL, and not a single one of the six urology practices in NJ listed in the article were delivering radiation therapy. This is consistent with academic reporting previously cited indicating increased utilization of IMRT to treat prostate cancer preceded the development of integrated urology.[22]

Perhaps the most important point that illustrates that IMRT utilization is not related to integration of these services by urology groups is the relationship between IMRT treatments for prostate cancer vs. IMRT treatments for diseases other than the prostate:[23]



	2005	2006	2007	2008	2009	2010	2011
Prostate	30500	36240	45420	45960	42800	44580	46860
Non-Prostate	26680	30920	37340	43080	49880	53000	56460

Figure 3: Utilization of IMRT to Treat Cancer of the Prostate vs. Other Diagnoses: 2005-11

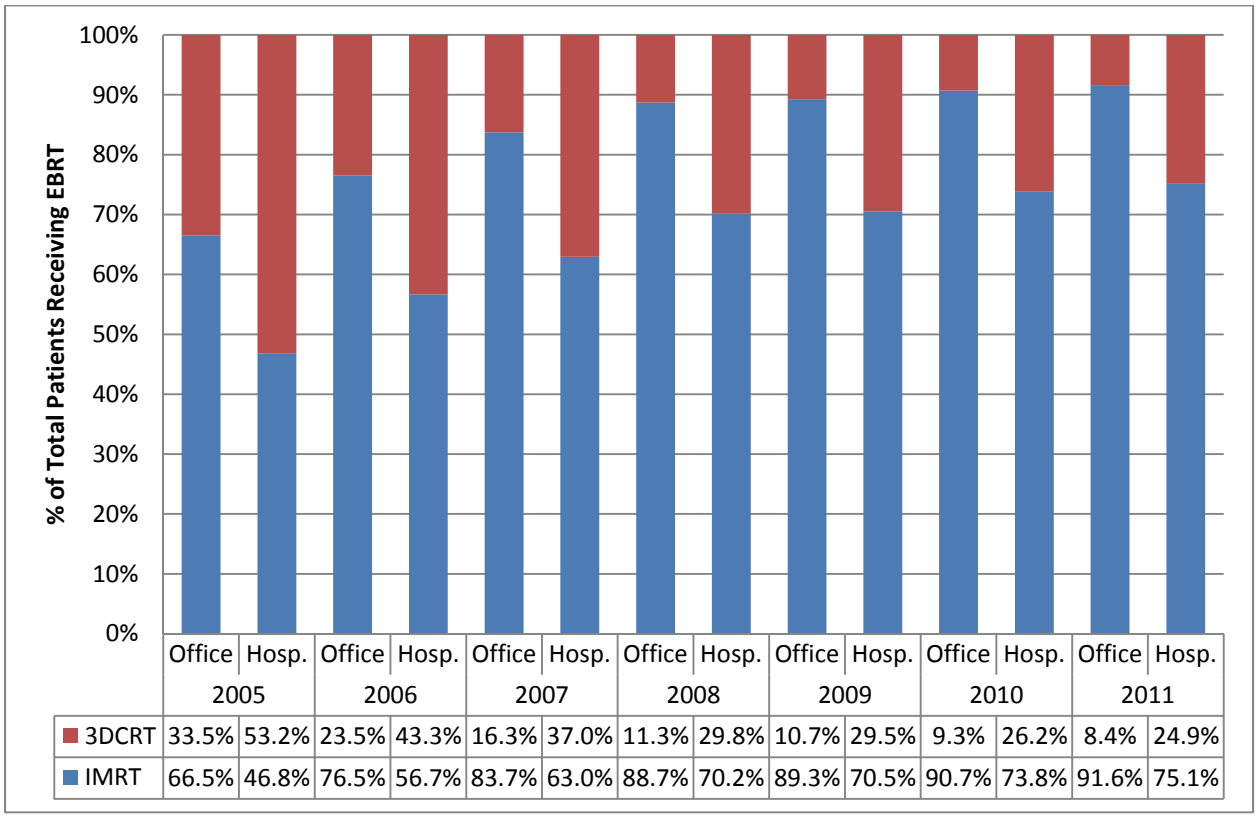
As can be seen, the growth of IMRT for prostate cancer expanded from 2005-07, but increased only slightly from 2007-11. In contrast, the growth of IMRT for non-prostate disease continued

[22]Nguyen PL, Gu X, Lipsitz SR, et al. Cost implications of the rapid adoption of newer technologies for treating prostate cancer. J Clin Oncol. 2011 Apr 20;29(12):1517-24.
[23] Op. cit., LUGPA 2013.

to increase steadily throughout this time period. In fact, by 2009, the use of IMRT for non-prostate disease exceeded that for prostate cancer. As prostate cancer is the malignancy most often treated by integrated urology groups, the growth in IMRT utilization for non-prostate disease cannot be attributed to ownership of radiation services by urology groups – further evidence that factors other than physician ownership are influencing treatment trends with regards to IMRT.

Physician Ownership of Radiation Improved Access to Superior Therapy

The clinical superiority of IMRT 3DCRT was documented well prior to the release of clinical guidelines affirming its use in the treatment of prostate cancer.[24] Given that this information was widely clinically available, an analysis of the relative probability of a prostate cancer patient to receive IMRT vs. 3DCRT based on site of service sheds light on quality of care rendered at those sites:[25]



	Office	Hosp.	Office	Hosp.	Office	Hosp.	Office	Hosp.	Office	Hosp.	Office	Hosp.	Office	Hosp.
	2005		2006		2007		2008		2009		2010		2011	
3DCRT	33.5%	53.2%	23.5%	43.3%	16.3%	37.0%	11.3%	29.8%	10.7%	29.5%	9.3%	26.2%	8.4%	24.9%
IMRT	66.5%	46.8%	76.5%	56.7%	83.7%	63.0%	88.7%	70.2%	89.3%	70.5%	90.7%	73.8%	91.6%	75.1%

Figure 4: Relative Utilization of IMRT vs. 3DCRT to Treat Prostate Cancer by Site of Service: 2005-11

This data reveals a dramatic difference in the quality of prostate cancer treatment received by patients in the hospital vs. the physician office setting – even by 2011, after consensus guidelines indicated that IMRT was superior to 3DCRT in the treatment of prostate cancer, *nearly a quarter of men treated at hospitals received older, more dangerous and less effective therapy than their counterparts who received treatment at a physician's office.* The likely explanation for this is

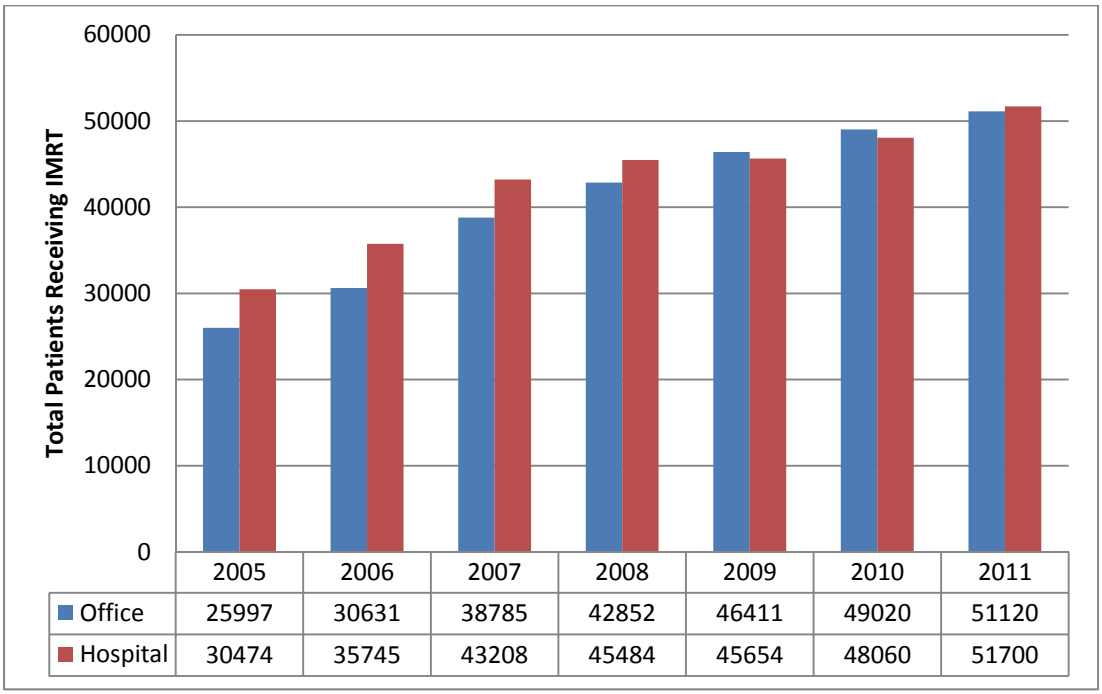
[24] Op. cit., Zelefsky 2002.

[25] Op. cit. LUGPA 2013. Note that the office setting in this graph includes both radiation oncology facilities operated by integrated urology groups as well as free-standing radiation oncology centers.

simply logistical: when a practice incorporates radiation technology, an investment is typically made in the most effective radiation oncology equipment. During the study period this was clearly IMRT; investment in equipment without such capability would be illogical for groups establishing *de novo* therapeutic radiation facilities. This is counter to the decision-making pressures faced by existing hospital radiation facilities where older equipment requires replacement or upgrading in order to deliver IMRT, and who treat diseases other than prostate cancer. Regardless of the reason, a substantially higher percentage of prostate cancer patients who received EBRT at the office setting received IMRT, what is clearly regarded as safer and more effective form of treatment for prostate cancer.

Physician Ownership of Radiation Oncology Does not Impede Competition

That hospitals have not been adversely impacted by physician ownership of radiation services is illustrated by the overall utilization pattern for IMRT for all diseases:[26]



	2005	2006	2007	2008	2009	2010	2011
Office	25997	30631	38785	42852	46411	49020	51120
Hospital	30474	35745	43208	45484	45654	48060	51700

Figure 4: Relative Utilization of IMRT vs. 3DCRT to Treat Prostate Cancer by Site of Service: 2005-11

This clearly illustrates that from a national standpoint, the relative ratio of patients treated with IMRT at the office vs. hospital setting has remained fairly constant over the recent past. Any local variations in IMRT delivery is likely the result of decision making by hospital administrators not to invest in enhanced technology either due to budgetary or space constraints – clearly there has been no restriction in the ability of hospitals nationwide to deliver these services if they are inclined to do so.

Summary

The principle purposes of CON regulations were to control utilization of expensive services as well as to encourage disease specific expertise by the development of loco-regional treatment

[26] Ibid, LUGPA 2013.

facilities. Unfortunately, these regulations have proven to be ineffective in either domain. Recent literature regarding utilization of radiation services to treat prostate cancer demonstrated that the rate of adoption of radiation technologies was *higher* in states with CON laws than in those without such regulations.[27] A study reviewing the results of both coronary artery bypass grafts (CABG) and percutaneous cardiac interventions (PCI, i.e. angioplasty) revealed that in over 3.3 million patients studied between the years 1989-2002, mortality rates for CABG procedures decreased in those states that dropped CON laws.[28] No change in outcomes was observed for PCI, and of note, the statewide procedure counts for both types of procedures remained constant.

Recently, investigative reports have shed light on a serious yet underreported problem: hospitals' role in perpetuating spiraling healthcare costs.[29] Differential reimbursement policies have enabled hospitals to acquire thousands of physician practices nationwide, consolidating their market control in many communities. Data suggests that once hospitals consolidate market share, they can extend bargaining leverage into enhanced rates with private payors as well, further driving up health care costs without producing any appreciable gains in quality or efficiencies of care.[30,31,32] Expansion of the regulatory burden on physician practices will adversely affect the delivery of healthcare - in addition to increasing costs, this will legislatively undermine the important competitive counterbalance provided by integrated physician groups.

Physician practices work to enhance quality by investing resources to broadly deploy electronic health records and by participating in PQRS and meaningful use initiatives; larger physician practices may be better able to develop infrastructure that allows for compliance with such programs.[33] Further evidence of this is seen in the timeline for the value based purchasing initiative as mandated in the Affordable Care Act – federal regulations require that medical practice groups comprised of 100 or more eligible professionals (as of October 15, 2013) will be subject to the value-based payment modifier in 2013.[34] Furthermore, in its June 10, 2010, report, the Medicare Payment Advisory Commission (MedPAC) acknowledged that the "potential benefits of clinically integrated practices, such as the capacity to provide comprehensive and coordinated care" must be considered in any future legislative strategy, and that clinically

[27] Khanna A, Hu JC, Gu X, et al. Certificate of need programs, intensity modulated radiation therapy use and the cost of prostate cancer care. J Urol. 2013 Jan;189(1):75-9.
[28] Ho V, Ku-Goto MH, Jollis JG. Certificate of Need (CON) for cardiac care: controversy over the contributions of CON. Health Serv Res. 2009 Apr;44(2 Pt 1):483-500.
[29] Brill, S. "Bitter Pill: Why Medical Bills Are Killing Us." Time. Mar. 04, 2013
[30] Melnick G, Keeler E. The effects of multi-hospital systems on hospital prices. J Health Econ. 2007 Mar 1;26(2):400-13
[31] Ciliberto F, Dranove D. The effect of physician-hospital affiliations on hospital prices in California. J Health Econ. 2006 Jan;25(1):29-38
[32] Cuellar AE, Gertler PJ. Strategic integration of hospitals and physicians. J Health Econ. 2006 Jan;25(1):1-28.
[33] Berman B, Pracilio VP, Crawford A, et al. Implementing the Physician Quality Reporting System in an Academic Multispecialty Group Practice: Lessons Learned and Policy Implications. Am J Med Qual. Epub before print March 12, 2013, doi: 10.1177/1062860613476733
[34] 2013 Requirement for Large Group Medical Practices Under the Value-based Payment Modifier; accessed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Self-Nomination-Registration.html March 25, 2013.

integrated practices "could be well-positioned to succeed under a new payment model."[35] At present, the National Conference of State Legislators reports that there are nearly 200 CON-related bills already introduced this year; at least 11 states are considering substantially easing or eliminating their existing CON regulations. CON laws are artificial constraints to the delivery of healthcare which ultimately serve to legislatively dictate winners and losers in the market. Healthcare should be provided at the site of service which provides the greatest access while simultaneously achieving the best outcomes at the lowest cost; easing or eliminating New York CON laws will serve to move towards that goal.

Respectfully Submitted

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[35] Medicare Payment Advisory Commission (MedPAC). Addressing the growth of ancillary services in physicians' offices. In: Report to the Congress: Aligning Incentives in Medicare. June, 2010, pp 213-237.

Excelsior Orthopaedics

March 25, 2013

Ms. Karen Lipson, Director
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Joan Cleary Miron, MPH, Director
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Dear Ms. Lipson and Ms. Miron:

On behalf of the 18 orthopaedic surgeons, physicians, and podiatrist in our practice at Excelsior Orthopaedics, and the surgeons and physiatrists working in the Buffalo Surgery Center ASC, I would like to take this opportunity to provide comments to you regarding the February 25, 2013 letter to health care providers which was sent as a follow-up to the Report of Certificate of Need (CON) Redesign and Health Planning. I am on the New York State Society of Orthopaedic Surgeons Board of Directors, a member of the American Academy of Orthopedic Surgeons (AAOS) Board of Councilors (advisory group to our National Academy), Catholic Medical Partners (CMP) Board of Directors, and CMP ACO Board. I have been previous Medical Director of the Buffalo Surgery Center and previous Orthopaedic Chair at Sisters Hospital in Buffalo.

Healthcare and medicine is changing and evolving. More integrated care coordination among providers through shared knowledge of patient and case information, better physician oversight of the quality of care being delivered, improved patient access, greater patient adherence to treatment plans with more integrated care models and less travel and delays in scheduling with "focused factories" are needed for improved health and reducing the cost of healthcare.

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This change in healthcare will require providers of various fields to adopt a more team based approach to care and some of the "enhanced physician groups" are able to do this. Rather than adding more restrictions, the focus should be on quality initiatives and ways to further integrate care and new care models.

I can speak on behalf of my group and organizations regarding surgical care, imaging services (including x-ray and MRI), and physical therapy. The GAO's recent report on imaging misrepresents and misallocates the cost of self-referred imaging. They use a radiology-based methodology which exaggerates self-referral even when scanning is appropriate. A recent study examining the imaging studies ordered by 2 large orthopaedic groups in Maryland before and after the implementation of a self-referral ban in that state showed no change in the ordering pattern of MRIs. This study is currently pending publication in the Journal of Bone and Joint Surgery. The quality of surgical care in surgery centers for outpatient procedures is better and with less complications and enhanced patient satisfaction than those performed in most hospitals.

Physician practice services such as surgery, radiation therapy, and imaging are significant because they have the opportunity to offer increased access to patients, more coordinated care with physician oversight, and particularly in more rural areas, may help provide better care and reduce disparities and improve public health. More coordinated care and easier access particularly at the physician offices, are associated with increased patient satisfaction and hopefully increased compliance with treatment and diagnostic plans because of ease of scheduling and improved access. Local initiatives for coordinated care are already being developed including ACOs and insurance panels which currently look at quality, cost and regional access. I think these initiatives should be allowed to develop regionally, but these regional entities are not appropriate everywhere. Mandating or legislating regional healthcare boards would be detrimental, costly, and allow for monopolies and possible restrictions of future care advancements.

1) Specifically, in the western region of upstate New York, enhanced physician practices increase access to care, provide excellent quality of care, are rated high in patient satisfaction surveys, do not add to cost, and potential decrease costs or are at least budget neutral.

2) Enhanced physician practices do not affect the operations or finances of our organizations. These models will be substantially utilized in

developing the ACO network as they are effective in increasing patient compliance and decreasing costs. Utilization will continue to be tracked by the insurance companies and in our local region, Catholic Medical Partners ACO.

3) Facilities and enhanced physician practices providing urgent care have improved access to care in our area and have high patient satisfaction. Urgent care centers that have a higher cost of care compared to their peers are deselected from insurance plans, and as we go forward with further transparency in costs and quality, any costly outliers will have to adjust to market forces. It is our opinion that market forces regionally should make those decisions and not have it legislated from the state level.

4) The Buffalo Surgery Center is an accredited Ambulatory Surgery Center and I do not believe the small amount of office-based surgery centers are affecting hospitals or surgery centers negatively in the upstate region. I think there are already appropriate oversights in New York regarding in-office surgery centers.

5) Enhanced physician practices providing advanced diagnostic imaging significantly improve access to care, have improved quality of care (because of the coordination of providers with shared knowledge of patient and case information), have reduced disparities because of increased compliance and improved scheduling for some of our more disadvantaged and vulnerable populations such as the elderly, and thus improved population health in the community. There are already appropriate regulating bodies controlling quality of care.

6) Enhanced physician practices providing radiation therapy have made it easier on patients and their family to get appropriate treatment with ease of scheduling and easier geographic access.

7) It is our group's opinion that New York State should not expand or significantly modify the criteria that define a diagnostic and treatment center under 10 NYCRR 600.8. Extending these regulations to a system that already needs streamlining and modification would significantly hurt physician practices in our community and possibly our organizations as well. This could significantly compromise the ability to get enhanced networks and care coordination encouraged regionally (including the local ACO) which would be detrimental to the population health in this area.

- A relaxation or discontinuation of the CON process should be considered to allow for and encourage formation of large, multi-specialty group practices and integrated care delivery models such as the patient centered medical home and accountable care organizations. These models are being proactive and incentivizing care coordination and payment incentives to improve quality of care while reducing overall health system costs. New York public policy should support the further development of these innovative models. CON processes should not be used by certain health system stakeholders to discourage the formation of these integrated, cost efficient, physician-driven health delivery systems. CON processes should not be expanded to create barriers to entry and expansion. There are significant administrative and legal costs incurred by both applicants and the DOH during the CON process that could be better used for patient care. Also, by protecting incumbents, restrictive CON programs may reduce the pressure on incumbents to improve their services and thus deny patients different and possibly higher quality treatment options and/or settings.

- New York should not require a CON for radiation therapy equipment regardless of the setting, advanced imaging equipment regardless of setting, or require a CON for in-office surgery.

8) The majority of physician organizations are professional corporations, professional limited liability partnerships, or professional limited liability companies. As such, these enhanced physician practices are consistent with the spirit of the prohibition by the New York's Education Law. The corporate practice of medicine doctrine ensures the medical practices should be owned and controlled by physicians. Larger medical group practices are necessary because increasingly, physicians are finding it economically difficult to continue to practice in solo or small groups. Larger or multi-specialty group practices provide a cost efficient and coordinated care setting through which healthcare can be delivered. 50% of new orthopaedic residency graduates are currently joining hospital systems. If the corporate practice of medicine doctrine is used to deter the development of larger group practices, a greater concentration of control of the practice of medicine will rest in the hands of a relatively few large hospital chains. It is my opinion that this will drive up the cost of medicine. Most studies show that if a physician in private practice joins a hospital as an employed physician, the physician then becomes 25% less productive, which will ultimately hurt access to care as there are physician

shortages in primary care and projected shortages in Orthopaedic Surgery with our aging and more active population. A loss of private practice physicians (regardless of the size of the group) would result in decreased population health and further disparities of care.

9) Urgent care providers are improving access and patient satisfaction, and while there is overutilization of emergency services in general, this needs to be addressed by appropriate level of care and coordination of care of which these entities will be beneficial going forward. Hospital emergency departments are not needed for many of these emergency visits and many of the urgent care facilities in our area are more cost effective than the Hospital emergency room.

10) I commend the Rochester area for their pilot project for a regional assessment advisory board. I think the results need to be looked at with true evidence-based medicine protocols, and see if there has been improved quality, value, and decreased costs before this process becomes legislated without appropriate vetting and further information.

If I or my organization can be of any further assistance, please feel free to contact me or the organization.

Sincerely,

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March 25, 2013

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Re: Stakeholder feedback for Department of Health recommendations to the PHHPC regarding Certificate of Need (CON) Redesign and Health Planning

Dear Ms. Lipson and Ms. Cleary Miron:

On behalf of New York Oncology Hematology (NYOH), we thank you for the opportunity to inform the Department's recommendations to the PHHPC. The proposals put forward in the PHHPC report on Certificate of Need (CON) Redesign and Health Planning—specifically *Recommendation #13: Update the criteria that trigger the facility licensure requirement and equalize treatment of physician practices and facilities with respect to CON requirements*—are important to our practice and our patients. We will outline in this letter why the demonstrated benefits and opportunities presented by "enhanced physician practices" (as defined by the PHHPC) in community cancer care—when physician-owned and governed such as NYOH is—far outweigh any claimed potential risks to the healthcare delivery system in the state. As such, it is our recommendation that the physician-owned and governed practices providing comprehensive cancer care in New York should not be subject to an expansion or modification of the criteria that define a diagnostic and/or treatment center under the CON program. As an affiliated practice of The US Oncology Network, our expertise on the understanding and provision of relative quality and cost advantages of physician-owned, integrated oncology practices is well established. We hope our recommendations will benefit the Department in providing objective recommendations to PHHPC as it considers both updating the criteria that trigger the facility licensure requirement, and equalizing the treatment of physician practices and facilities with respect to CON.

America's Cancer Care and the Integrated Model

While cancer is an all-consuming disease that affects 3 out of 4 families in America, we also enjoy the world's best cancer care.[1] Residents of the US have cancer survival rates higher than the average in Europe and Canada for 13 of 16 types of cancer. At the core of this excellent care is integrated community oncology—medical, radiation, and surgical oncologists practicing or

[1] http://www.ncpa.org/pub/ba649

working together, as a well coordinated team, in physician-owned, community-based cancer centers. Nearly 80% of all US cancer patients receive their care in the community setting, where the most advanced care is brought together by a team of oncology specialists working collaboratively for the benefit of their patients. Approximately 7,500 community-based oncologists carry the burden of treating over 1.5 million cancer patients in the United States each year. Meanwhile, the rate of increase in cancer treatment spending is expected to increase as the population ages, more cases are diagnosed and treatment becomes more expensive relative to other disease categories. In a 2010 study, Milliman reported that in 2007, a cancer patient receiving chemotherapy incurred average costs of approximately $111,000.[2] In 2011, the National Cancer Institute released projections of the cost of cancer care in the US, finding the total cost of cancer care in 2020 is expected to be $173 billion, up 39 percent from 2010, when it was estimated to be $125 billion.[3] The majority of cancer costs are related to cancer patients receiving chemotherapy, not diagnostic imaging or radiation therapy. Forty percent of drug spending for Medicare patients is on drugs prescribed by an oncologist, excluding administration charges for chemotherapy.[4] It is important to note the prevalence of cancer varies by age and gender. As the Baby Boomer population moves into retirement age, the prevalence of cancer will increase among this population. According to a review of Surveillance, Epidemiology and End Results (SEER) from the National Cancer Institute (NCI), women—who outlive their male counterparts—have a higher prevalence of cancer than men as they reach advanced ages. In light of these demographic shifts and expected increases in cancer prevalence, the cost of cancer care to our nation will continue to increase.

The primary cost drivers in oncology are multifaceted, as is the care that is provided. The macroeconomic trends can primarily be tied to 3 areas: 1) The variation and cost of treatment, particularly chemotherapy and supportive care agents; 2) The use of emergency care services associated with the degradation of patient health status throughout treatment, often from preventable complications; and 3) The over-utilization of intensive medical intervention near the end-of-life.

The challenge then—across all settings—is to cost-effectively utilize new treatments and technologies in an evidence-based fashion when they are able to most positively impact patient care and quality of life. In other words, bringing quality and value to cancer care, where quality is the efficient delivery of evidence-based care by trained clinicians in an accessible setting, and value is providing higher quality care at the same cost, or the same quality care at a lower cost. Improvement in quality and reduction in overall cost can be achieved by reducing variation in several utilization and cost measures. Targeting the following utilization and cost metrics can demonstrate the most effective means for cancer care management: 1) Cancer-related drug costs; 2) Chemotherapy-related hospitalizations; 3) Chemotherapy-related emergency room visits; and 4) Dying in hospital and chemotherapy administration within 2-4 weeks of dying.

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[2] Milliman Client Report: Cancer patients receiving chemotherapy: Opportunities for better management. March 30, 2010. Bruce Pyenson and Kate Fitch. http://publications.milliman.com/research/health-rr/pdfs/cancer-patients-receiving-chemotherapy.pdf

[3] Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, and Brown ML. Projections of the Cost of Cancer Care in the United States: 2010-2020. Jan 19, 2011, JNCI, Vol. 103, No. 2. http://jnci.oxfordjournals.org/content/103/2/NP.2.full

[4] Ries LAG, Harkins D, Krapcho M, Mariotto A, Miller BA, Feuer EJ, et al. (eds). SEER Cancer Statistics Review, 1975-2003, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2003/, based on November 2005 SEER data submission, posted to the SEER web site, 2006.

Spending on cancer now accounts for about five percent of all medical treatment in the U.S. and about ten percent of Medicare spending. However, over 40 percent of Medicare drug expenditures are for oncology/hematology drugs. The disproportionate cost of cancer drugs has been the topic of much discussion as a factor in increasing cost of care. Cytotoxic and biologic agents are some of the most expensive drugs to develop, with no decrease in sight. According to a recent study, the cost of bringing a new cancer drug to market, including pre-clinical and clinical testing, is approximately $1 billion.[5]

Community cancer care is not only the most preferred site of care for patients, but it is also demonstrably the most cost-effective. An October 2011 Milliman study shows the total cost of fighting cancer is significantly lower for both patients (10 % lower in co-pays, more than $650/year in savings) and the Medicare program (14.2% less, a savings of $6,500/year/patient) when managed in the physician office setting versus the hospital outpatient setting. [6] In April 2012, a study released by Avalere Health found that chemotherapy provided in a physician's office costs on average 24% less than chemotherapy provided in the hospital outpatient setting. [7] The Avalere study also showed that radiation therapy treatment episodes lasting 1 and 2 months and were provided to cancer patients in the physician office setting were between 7% and 17% less expensive respectively than similar hospital outpatient-managed episodes of radiation therapy.

The effectiveness of the integrated model of care—one that brings the entire continuum of care (radiation therapy, chemotherapy, surgery, diagnostic imaging, clinical trials, etc.) together close to where patients live and work—has contributed to the community setting proliferating as the most-preferred setting for cancer treatment, and it is the integrated model leading the drive to deliver more quality and value in cancer care. With community-based cancer care being the most cost-effective setting in which cancer patients can be treated while maintaining equivalent health outcomes, the federally established ability for physicians to assemble ancillary services—principally, with regard to this discussion, advanced medical imaging and radiation therapy—has been crucial to advances in delivering quality and value to cancer care. When patients have the ability to choose a practice where they can receive all aspects of their care in one outpatient facility, they are able to save time, convenience, out-of-pocket costs, and better cope with—and heal from—a disease as uniquely devastating as cancer can be. In the integrated setting, their care is less fragmented, travel times are reduced, suffering is reduced, and their costs are reduced as well.

And it is no coincidence the resulting patient outcomes have also improved along with the shift in the provision of the continuum of cancer treatment out of the hospital setting and into the integrated physician practice. It is convenient for the patient, fosters better patient-physician communication, allows better collaboration among the members of their oncology care team, and still insures quality and patient safety are not sacrificed.

With the ability of integrated community cancer centers to offer advanced diagnostic imaging and radiation therapy services together in the same setting, the need for quality assurance and patient

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[5] Adams CP, Brantner W. Estimating the cost of new drug development: is it really $802 million? Health Affairs 2006;25:20-428.

[6] Milliman Client Report: Site of Service Cost Differences For Medicare Patients Receiving Chemotherapy. October 19, 2011. Kate Fitch and Bruce Pyenson. http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf

[7] Avalere Client Report: Total Cost of Cancer Care Site of Service. March 2012. http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf

safety standards for imaging services remains just as important as in the hospital setting. For NYOH, it is second to none, with facilities fully accredited by the American College of Radiology (ACR), as is required by Medicare. And as with the imaging services, radiation therapy services provided in the physician office setting meet the highest accreditation standards as established by the ACR. This is done to ensure: 1) they meet nationally accepted standards of care; 2) they have personnel well qualified through education and certification to administer radiation therapy; and 3) their equipment is appropriate for the prescribed treatment regimen. ACR accreditation standards have been established to guarantee patient safety and treatment quality.

According to a recent analysis[8] of American Cancer Society data, medical imaging technologies—such as computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET)—contribute to America's continually declining cancer mortality rates. In particular, death rates continue to decline for lung, colorectal, breast and prostate cancers. The ability of cancer patients to access these diagnostic services at physician practices close to home, as part of an integrated cancer care team, has increased greatly over the past decade—at the same time that improvements in cancer survivorship have increased. Indications are the correlation is not coincidental.

It is not surprising that when pieces of the continuum of cancer care are reviewed individually there have been concerns expressed regarding possible self-referral, overutilization, or supply sensitivity. However, it cannot be forgotten that with the many of the current, most-effective treatment options for commonly occurring cancers being "dual-modality" (involving combinations chemotherapy and radiation therapy used in combination, and sometimes in very close time-proximity to one another, often needing advanced diagnostic imaging as well, to help accurately stage the disease) it would be nearly impossible to perform such procedures in the lower-cost, physician practices without the ability for physicians to assemble ancillary services together, in-office.

Threats to America's Integrated Cancer Care

Despite studies indicating that community-based cancer care lowers costs to patients and Medicare (which covers nearly half of all cancer patients), a series of cuts to Medicare reimbursements for cancer care has destabilized the cancer care delivery system already under stress due to previously inadequate Medicare payment and a system Medicare policies of reimbursement inequity based on care settings.

According to a current report[9] issued by the Community Oncology Alliance (COA), more than 1,250 community based cancer clinics/practices during the past 4½ years have been impacted either by closures, acquisitions/mergers, financial struggles, or having to send patients elsewhere.

- 241 Clinic sites closed
- 442 Practices struggling financially
- 47 Practices sending patients elsewhere
- 392 Practices either acquired by a hospital or entered into a hospital agreement
- 132 Practices either merged together or were acquired by a corporate entity, other than a hospital.

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[8] http://www.medicalimaging.org/2013/01/17/new-american-cancer-society-report-shows-medical-imaging-technologies-contribute-to-declining-u-s-cancer-death-rate/

[9] http://glacialblog.com/userfiles/76/Community_Oncology_Practice_Impact_Report_4-4-12F.pdf

It is important to note that it is the community oncology physician-owned practices being hit especially hard. There was a 20% increase in the number of community oncology physician-owned practices impacted from a year ago, including a 21% increase in clinics closed, a 20% increase in practices struggling financially, a 24% increase in practices with a hospital agreement or purchase, and a 19% increase in practices merged or acquired. And all of this is before the effects of sequestration (another 2% cut to Medicare across the board) hit in full force beginning April 1st.

We continue to see consolidation in the cancer care landscape. This is primarily the result of Medicare reimbursement, which is insufficient in covering the costs of cancer care. Medicare is the largest payer of cancer care, with close to 50% market share, and has substantial market clout in influencing private payers. Moreover, failure to fix the Sustainable Growth Rate (SGR) has created tremendous uncertainty that impedes business planning and threatens practice viability. A study by Avalere Health shows that Medicare covered only 57% of the costs of cancer treatment services in 2009. Additionally, an increasing number of cancer drugs are reimbursed by Medicare at less than cost because of factors such as the artificial reduction in Medicare drug reimbursement due to the prompt pay discount problem. Inclusion of manufacturer-to-distributor prompt payment discounts, not passed on to oncology clinics, artificially decrease drug payments and continue to undermine the viability of physician-owned practices.

Medicare policy exacerbates the shift of cancer care to the hospital setting by paying differently for the same treatments depending on site of service. The 2012 physician fee schedule (PFS) fate for CPT Code 96423, Chemo, iv infusion, 1 hr—the most common drug administration code billed by oncology practices—is $139, but the payment rate for the same service under the 2012 HOPPS fee schedule is 50% higher, at $208. Utilization-weighted payment for infusion services is about 55% higher at the hospital outpatient department (HOPD) setting. For radiation therapy services, Medicare proposes in 2013 to pay the HOPD 25% more than the PFS, including a 70% differential for IMRT and a 188% differential for SBRT. Additionally, one-third of US hospitals purchase chemotherapy drugs through the 340B program at discounts of up to 50%, typically 30+% below the reimbursement rate of ASP+6%. Finally, Medicare reimburses 70% of hospital bad debt, or uncollectable coinsurance, while reimbursing none for physician-owned practices.

As documented by recent Milliman[10] and Avalere[11] studies, oncology consolidation into the non-physician-owned setting will increase costs to cancer patients, Medicare and taxpayers, and private insurers, and subsequently employers. Cancer patients will increasingly be forced into treatment at hospitals, either through their emergency departments, inpatient, or outpatient facilities, increasing costs significantly on the entire health care system. This will result in a further undermining of patients' access to integrated care, either through a lack of financial means or a lack of provider capacity, which will in turn reduce patient outcomes and eventually risk our nation losing ground in the "War on Cancer" for the first time since it began more than 40 years ago. Rural areas, like Upstate New York, will be especially hard hit by treatment access problems for cancer patients. According to the COA report, New York had 61 practices impacted: 8 closures, 42 practices struggling financially, and 7 more entering operation or purchase agreements with hospitals.

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[10] Milliman Client Report: Site of Service Cost Differences For Medicare Patients Receiving Chemotherapy. October 19, 2011. Kate Fitch and Bruce Pyenson. http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf

[11] Avalere Client Report: Total Cost of Cancer Care Site of Service. March 2012. http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf

In this challenging environment, with the access to low-cost treatment for cancer patients in New York already under such threat because of unsustainable policies at the federal level, updating the criteria that trigger the facility licensure requirements to include physician practices, and equalizing the treatment of physician practices and facilities with respect to CON requirements, would undoubtedly add substantial additional costs for physician practices—costs which can logically be assumed to be unbearable in addition to current stressors.

The US Federal Trade Commission and Department of Justice (FTC/DOH) has recognized the CON approval process as impeding the delivery of care, and as such have supported the repeal of such laws. The FTC/DOJ testified that "By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers. They undercut consumer choice, stifle innovation and weaken the markets' ability to contain health care costs".[12]

The FTC and DOJ believe that CON programs can pose serious competitive concerns that can outweigh CON programs' alleged benefits. Where CON programs are intended to control health care costs, there is evidence that they can actually drive up prices by fostering regulatory barriers to entry, which by their nature are an impediment to health care competition. By protecting applying CON to the lower-cost community cancer practices, the program would deny patients different, and more affordable, high-quality treatment options or settings. The proponents of CON overstate the alleged savings coming from such programs by not offsetting purported savings with a number of the significant costs incurred by both CON applicants and the State of New York during the course of the CON process. Fourteen other states have repealed CON statutes, and most of the remaining CON states have greatly modified aspects of the programs to encourage more competition and innovation in delivery. Objective thought and consideration must be given to any future CON redesign and planning processes, to ensure that private practice community cancer centers are not rendered at risk and financially vulnerable due to the significant market influences that other providers may bring to bear. Without access to community cancer care, patients experience higher copayments; longer travel times and increased travel expenses; visits to multiple providers and locations for care and services; and delays seeking treatment even as their cancer progresses.

New York Oncology Hematology

New York Oncology Hematology (NYOH) is the Upstate New York region's leading provider of community-based cancer care services. The physicians and staff of NYOH are committed to reducing the incidence of cancer and blood diseases through earlier detection and intervention and offering their patients the most appropriate, evidence-based treatment options. NYOH operates seven patient-convenient locations, including five comprehensive, fully-integrated cancer centers, and it is through this network of community-based centers that NYOH provides world-class care to thousands of patients every year—close to where our patients live and work. Through our affiliation with The US Oncology Network, one of the nation's largest integrated oncology networks, NYOH has played a pivotal role in not only the provision of world-class cancer care services to the Upstate New York Region, but also the FDA approval process of 24 new anticancer drugs, cost savings to patients, employers, and payers, as well as bringing shared best practices and evidence-based medicine pathways to our patients. Our special approach to cancer care allows us to

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[12] Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform (September 2008).

have the best minds working together to develop new treatments, achieve more cures, bring treatment breakthroughs home, and constantly enhance patient health, experience, and satisfaction.

The US Oncology Network (The Network) is the nation's leading integrated oncology organization, uniting one of the largest community-based cancer treatment and research networks in America. The Network offers expanded patient access to high-quality, advanced care and has continually advanced the science of cancer care. Affiliated with nearly 1,000 community-based oncologists, The Network works with patients, payers, and the medical industry across all phases of the cancer research and delivery system. Through the use of innovative technology, clinical research, evidence-based medicine, and shared best practices, The Network helps practices like NYOH improve patient outcomes and offers a better patient experience.

NYOH has expanded patient access to high-quality, advanced cancer care through use of components of The Network's comprehensive evidence-based medicine and patient care program, Innovent Oncology. Building upon physician and clinician expertise to create value in cancer care, Innovent Oncology uses a powerful reporting and analytic platform to increase efficiencies and reduce treatment variability across the entire patient care continuum. By applying The Network's well-defined Level I Pathways evidence-based treatment guidelines, proactive patient care management and support, and advance care planning, physicians can enhance the quality and consistency of patient care delivered in communities throughout the nation, including the Upstate New York Region. The program also strives to align incentives between providers and payers to produce better patient care and an improved patient experience, enabling practices like NYOH to lower costs for patients and payers while enhancing care and matching the patient outcomes of other settings.

NYOH utilizes the core components of Innovent Oncology to provide optimal patient care while retaining flexibility in treatment options and independence as a physician-owned and governed, community-based oncology practice. These components include: addressing regional variation in drug ordering patterns by physicians through electronic clinical decision support tools; reinforcing the decision to use chemotherapy only when there is scientific evidence to support clinical benefit; documenting adherence by physicians to accepted Level I Pathways recommendations; documenting off-pathway exceptions for evaluation; providing Patient Support Services through oncology-certified nurses to minimize complications associated with chemotherapy; and introducing and facilitating Advance Care Planning based on each patient's values and goals. NYOH's participation in The Network results in improved cost-effectiveness and consistent patient management, while maintaining quality cancer care for the individual patients in the Upstate New York Region.

The foundation of the care we provide to our patients comes through our practice of Level I Pathways, which are evidence-based guidelines that limit the wide variances responsible for tremendous cost disparities in the delivery of cancer care today. Clear and credible clinical standards, developed by practicing community-based oncologists across the nation, are the basis for effective treatment selection and quality patient care. Reportable treatment comparisons identify provider compliance and facilitate performance-based reimbursement.

Level 1 Pathways promote use of evidence-based medicine; encourage use of generics, when appropriate; prioritizes chemotherapy regimens with the best efficacy and least possible toxicity; and assesses drug costs and include analysis of the least costly option, if there are acceptable efficacy and safety profiles for the regimens. Level I Pathways have been developed according to

process and procedure standards, and are agreed upon and continually updated by The Network and its network of oncologists. The program has been proven to deliver high quality, high value care.9 Additionally, the potential value of adherence to Level I Pathways has been shown by an independent actuarial firm to reduce: 1) hospitalization due to chemotherapy complications, 2) chemotherapy costs, and 3) total costs.10,11 Evidence for creating Level I Pathways is obtained from the review of well-designed clinical trials. Level I Pathways have been developed and are routinely updated by a multi-disciplinary committee, the Pathways Task Force, in collaboration with a network of nearly 1,000 practicing community-based medical oncologists. Any oncologist engaged in delivery of patient care using the Innovent Oncology program can participate in the development and utilization of Level I Pathways.

With access to Patient Support Services (PSS), NYOH physicians have the ability to deliver proactive disease management services to patients between office visits. This personalized patient support increases adherence to the treatment plan and reduces unplanned emergency room visits and hospitalizations, a major cost driver in cancer care. Patient Support Services include planned contact by oncology certified nurses for each patient between chemotherapy treatments; early, proactive interventions with scheduled nursing contact; standardized symptom grading methods, including depression screening, activities of daily living assessment and pain assessment; documentation occurs within an integrated electronic health record; early exploration of a patient's goals for end-of-life care; referral back to practice for side effect management and/or intervention; and electronic health record interface for documentation exchange and coordination with oncology practices.

Advance Care Planning (ACP) assists the NYOH oncology care team in preparing patients for disease progression and documents patient treatment preferences, including palliative care and hospice. This proactive approach eases patient distress, increases satisfaction with care, and ensures more appropriate services utilization. About 27 percent of Medicare's annual budget goes to care for patients in the final year of life. The 2006 Dartmouth Atlas of Health Care reveals in detail that more is not better when it comes to end-of- life care.[13] That said, determining how much is too much is challenging. It must begin with end-of-life discussions. A recent study showed that despite physicians' concerns that these discussions may cause psychological harm for their patients, patients who had these discussions were more likely to forego aggressive medical treatment, use hospice care, and experience improved quality of life.[14]

Advance Care Planning includes a well developed, systematic Advance Care Planning (ACP) program with the ability to document advance care directives and other end-of-life choices. Services are provided in collaboration with oncologists' practices by oncology certified nurses are trained to facilitate the program. Physician introduced and endorsed informational materials start the ACP process with the patient. Discussions of ACP are initiated early during the initial assessment and followed up and documented throughout treatment. All patients are encouraged to develop an advance care plan which creates a vehicle to communicate wishes to the care team and family and empowers patients and families to control care at end-of-life. The ACP program also includes ongoing follow-up for terminally-ill patients who wish to transition to hospice.

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[13] Dartmouth Medical School Center for Evaluative Clinical Sciences. The care of patients with severe chronic illness: an online report on the Medicare Program by the Dartmouth Atlas Project, 2006, p6.

[14] Wright, AA et al. Associations between end-of-life discussions, patient mental health, medical care near death and caregiver bereavement adjustment. JAMA 2008; 300(14): 1665-73.

The results of utilizing these components can be remarkable for bringing quality and value into oncology care for the Upstate New York Region. In two separate studies, the value of Level 1 Pathways has been proven to lower costs while maintaining equivalent health outcomes.

A joint study[15] with Aetna published in the January 2010 *Journal of Oncology* found that costs were 35% lower for non-small cell lung cancer patients treated according to Level 1 Pathways while maintaining patient outcomes. A similar study[16] published in a special joint issue between the peer-reviewed *Journal of Oncology Practice* and the *American Journal of Managed Care* in May 2011 found that evidence-based care for patients with colon cancer results in equivalent health outcomes and total cost savings of more than 30 percent, $53,000 for the treatment of adjuvant colon cancer and $60,000 for the treatment of metastatic colon cancer. Additionally, a pilot study[17] recently reported at the American Society of Clinical Oncology's Quality Care Symposium showed that in the first twelve months of treatment, patients treated using the components of the Innovent Oncology program had almost 40% fewer emergency room visits, 16.5% fewer inpatient admissions, and about 36% fewer inpatient days compared with other newly diagnosed cancer patients in Texas.

Recommendations

In the report *Trends and Changes in the New York State Health Care System: Implications for the CON Process,* developed by the United Hospital Fund[18] for the Department, in reflecting on the CON's role and impact in the future, it was noted that "particularly as providers move toward accepting risk, excess facilities and services will be seen as driving costs more than generating revenues. In such a scenario, CON would probably have a less important role." In essence, if providers will be paid an agreed-to amount based on the health outcomes of their patients, the incentive to develop excess capacity will be effectively nullified.

Given the passage of health care reform in the Affordable Care Act, and its implementation being well underway, our nation's healthcare system is already moving away from a FFS based payment system toward a value-based reimbursement system. This is the direction that NYOH is moving toward through its work with The US Oncology Network, and, as demonstrated through the above referenced studies, the results are significant. Indications are that this is the direction that cancer care overall must move in order to ensure the future viability of health care financing going forward.

With Medicare reimbursements being woefully inadequate, Medicare and private payers currently experimenting heavily with Accountable Care Organization (ACO) models, and with the ACA's provisions allowing for the possibility of specialty-specific ACO pilot programs, the era of FFS payment for cancer care is rapidly coming to an end.

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[15] Neubauer MA, Hoverman JR, Kolodziej M, et al. (2010) Cost effectiveness of evidence-based guidelines for the treatment of non-small-cell lung cancer in the community setting. J Oncol Pract 6:12-18. http://jop.ascopubs.org/content/6/1/12.short

[16] http://jop.ascopubs.org/content/7/3S/52s.abstract

[17] http://journals.lww.com/oncology-times/Fulltext/2013/01100/How_Oncologists_Are_Bending_the_Cancer_Cost_Curve.2.aspx

[18] http://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report_appendix_e.pdf

As a result, we believe the PHHPC's Recommendation #13 is not only unnecessary with regard to its possible application to community oncology and integrated physician oncology practices, but we also believe to apply CON process requirements to such physician practices at this time of budding payment reform innovation could further strain the financial viability of integrated, high-value cancer care providers like NYOH, and thus further limit patient access to the world's best cancer care. We recommend the Department carefully consider the relative quality and cost of radiation therapy and imaging services in the integrated community oncology physician practices setting holistically—including the entire continuum of cancer diagnosis and treatment tools that can be brought together to benefit cancer patients, as we have demonstrated in this letter—and in relation to the higher costs of what the continuum of care would cost the entire healthcare system if these cancer patients were treated at the hospital or hospital outpatient department setting.

Sincerely,

New York Oncology Hematology, PC

By: 

Nancy Izzo, Director of Operations
For Nini C.Y. Wu, President

orthoNY Your bone and joint experts

March 25, 2013

Ms. Karen Lipson, Director
Division of Policy, Office of Health Systems Management
NYS Department of Health
Corning Tower
Albany, NY 12237

Joan Cleary Miron, MPH, Director
Division of Primary Care Development, Office of Primary Care
NYS Department of Health
Corning Tower
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Dear Ms. Lipson and Ms. Miron,

This letter is in response to yours of February 25, 2013 related to the growing market presence of single- and multi-specialty "mega" physician practices. Ortho New York (OrthoNY) is a 27-physician practice working out of both the Capital and Saratoga regions. We merged two orthopaedic practices together in January, 2013 to bring greater benefits and services to the communities we serve. I would like to respond to some of the questions you raise in your letter to give you a large group perspective on moving forward.

OrthoNY now has offices covering many counties in Northeast New York. Through our centralization, we have been able to consolidate our business office and are looking to reduce costs over time. Our philosophy is to grow our business by moving into communities where orthopaedic surgeons are in short supply or where the current surgeons are "aging in place." In the latter situation, we hope to move ahead of the likely future of an orthopaedic shortage. As you probably know, the demand for orthopaedic surgeons is slated to grow in the next decade or two due to both the aging of the population as well as the continued healthy lifestyles of our baby boomers.

In-office access to high-quality imaging equipment is critical to our ability to effectively treat our patients and to recruit new surgeons. If we were restricted or delayed in obtaining this equipment by the CON process, our patients would experience delays in treatment and our practice would experience difficulty in recruiting new orthopaedic surgeons into our practice. Since the growth of our practice is currently focused on underserved areas in Upstate New York, the current trend in the shortage of specialists in some counties would continue.

OrthoNY has also been able to bring valuable services to the communities we serve. Not only are the services high quality, they are also lower cost, thereby securing a positive cost/value equation. We have done this with the introduction of MRI services and the

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development of an ambulatory surgery center, services that have been evaluated and accredited by outside entities (ACR and AAAHC, respectively) and that have also been acknowledged as low-cost services by area insurers. These services provide a one-stop medical shopping experience for our patients and have resulted in high patient satisfaction.

OrthoNY does not believe that inhibiting the introduction of new services with an expanded certificate of need process makes any sense. In this day and age, it is important that all health care organizations be able to respond and react to the quickly changing health care environment. As new rules and regulations are promulgated and as competitive forces continue to change the healthcare landscape, all organizations need the ability to introduce creative new services for our patients. We feel that the CON process should be reduced or eliminated, not expanded, leveling the playing field for all of our health care partners.

Finally, OrthoNY is working closely with our hospital partners to improve the quality of service provided and to reduce the cost of providing that care. We have recently entered into a service line co-management agreement with St. Peter's Hospital and are hoping to begin a similar service with Saratoga Hospital. In these new relationships, the physicians have the ability to participate fully in both the planning and operational aspects of the orthopaedic service. By aligning the goals of both the hospital and the physicians, the value equation will be greatly enhanced.

In summary, OrthoNY does not believe that the expansion of the CON process to "mega" groups makes any sense. It will slow down innovation and actually increase the cost of care. It would be far better to allow those currently subject to CON regulations to be freed of this regulatory burden and to let the competitive processes forge the market.

If you have any questions regarding our comments, please feel free to call me at [redacted]. Thank you for the opportunity to respond.

Sincerely,

Alan Okun, FACHE
Chief Executive Officer

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Catholic Health

March 25, 2013

Ms. Karen Lipson & Ms. Joan Cleary Miron, MPH
Divisions of Policy and Primary Care Development
New York State Department of Health
ESP – Corning Tower
Albany, NY 12237

RE: PHHPC's Request To:
Update the criteria that trigger facility licensure requirement and
Equalize the treatment of physician practices and facilities with respect to CON

Dear Ms. Lipson and Ms. Miron:

Catholic Health in Buffalo, New York thanks you both for the opportunity to comment on the State Public Health and Health Planning Council's request for recommendations to update the criteria that trigger the facility licensure requirement and equalize the treatment of physician practices and facilities with respect to Certificate of Need.

Catholic Health has long voiced concern along with other healthcare systems across NYS over the fact that Article 28 providers are required to demonstrate need, character/competence, financial feasibility and code compliance through the Certificate of Need (CON) process before being allowed to establish new sites of service while physicians can freely add services with little to no oversight and do not have to go through the CON process. Additionally, the State expects services approved through the CON process to be available to all people regardless of the type of insurance they have. This expectation insures that individuals with Medicare, Medicaid and no insurance will have access to medically necessary services.

As a mission-based healthcare system, Catholic Health has always provided services to all people regardless of their ability to pay. As an Article 28 provider, we are required to make our services available to all. Private physician practices do not have the same obligation to care for all regardless of their ability to pay. This is where disparities in healthcare access become noticeably apparent.

Private Physician Practice's Affect

In our community, we believe that many private physician practices that offer urgent care, office-based surgery, advanced imaging and radiation therapy are targeting their services to the commercially insured and "better" paying patients. These patients are satisfied with the access and quality of care they receive. For uninsured, Medicaid and "poorer" paying patients, none of these criteria are improved as these patients typically have limited access to these privately owned sites of service due to their limited financial resources.

In many cases, the services offered by private physician practices are duplicative to services that currently exist in the community. When duplicative, the overall costs to the healthcare system are increased not only by having additional sites of service when capacity may already exist, but by the potential of having over-utilization based

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on the theory that supply generates demand. Private physician practices typically target the commercial population which tends to be a younger, healthier, more educated, and higher income-based population. They tend to be the healthier, lower cost cases in the community at large. By disproportionately pulling these lower intensity cases to the private physician practices, the regulated health systems are by default left with a greater percentage of the older, less healthy, less educated, lower income based population which tend to have a higher prevalence of chronic diseases and higher costs overall.

Because of this fact, these private physician practices that compete with services we offer are negatively impacting the financials of our organizations as they typically attract the commercially insured, better paying patient base. As a result, our sites receive less of the "better" paying patients to help off-set the costs we incur to care for all patients including those with no ability to pay at all.

To "equalize" the treatment of these physician practices with our and other Article 28 facilities, we would recommend adding CON review to these practices versus eliminating CON in total to all providers. We believe eliminating CON in total will negatively impact the access that currently exists for the less fortunate and "poorer" paying patients.

Diagnostic and Treatment Center Criteria 10 NYCRR 600.8

Department of Health regulations at 10 NYCRR 600.8 set forth criteria that define the operation of a diagnostic and treatment center and trigger CON and licensing requirements whether or not a health care provider is organized as a physician practice. These criteria could easily be expanded by adding services similar to how the state added ambulatory surgery to the criteria. We would suggest the State include expectations that providers must meet utilization percentages equal to that service's County Medicaid/uninsured average so all providers share in caring for those who are less fortunate improving access to all (similar to the expectations posed upon nursing home providers). Services to be added could include all those provided by a hospital, but should start with the higher cost, higher technical services such as radiation therapy and advanced imaging. Because physicians may currently provide these services within their office settings, the State should consider relaxing their "co-location of space" rule/policy to allow these services to continue to be offered with State oversight. Relaxing this rule/policy will also help health systems provide more collaborative service solutions which are prohibited from being provided today.

New York's Education Law/Captive PC

Enhanced physician practices that provide a comprehensive array of diagnostic and treatment services do not seem to be structured to be consistent with the spirit of the prohibition of New York's Education Law. Today, advances in medicine are moving many services that were once only provided in a hospital setting into the community and into physician practices.

Additionally, the concept of a "Captive PC" being a corporation that controls a licensed professional is also not consistent with the spirit of the prohibition. It appears as though a "Captive PC" and enhanced physician practices that provide diagnostic services are simply means to maneuver around regulations at 10 NYCRR 600.8.

Non-Hospital Urgent and Emergent Care

As stated on page 1, in our community non-regulated urgent care providers (similar to other private physician providers) are providing greater access to services for those who have the financial means either through insurance or out of pocket. These sites are affecting our organization because in many cases they are strategically locating to draw from our ED traffic. While they do provide a lower cost setting to our EDs, they are

able to be more cost effective since they are not required to be open 24/7 but typically are open 9 am – 9 pm. These providers could be regulated by adding this service to the list of criteria that defines a diagnostic and treatment facility. Having these providers in the community would be beneficial from a population health standpoint as it gives patients a lower cost option to seek treatment for urgent care needs (assuming the costs of care are lower than ED costs).

Community Technology Assessment Advisory Board

As it relates to the effectiveness/value of having an Advisory Board that comments on the need for new technology and specialized services, we believe that it would be challenging to create an Advisory Board that was impartial in our area. In this day of new collaborations between payors, providers and physicians, it is highly unlikely that there will ever be a body that could be fair and unbiased since historically these types of organizations have been co-opted by persons/agencies with self-serving agendas.

Thank you again for the opportunity to comment. If you have any questions, please do not hesitate to call me directly. I can be reached at [redacted]. Thank you again.

Sincerely,

Maria A Foti

Maria A. Foti
Senior Vice President, Planning

CC: Joseph D. McDonald, President and CEO, Catholic Health
Dennis Horrigan, President and CEO, Catholic Medical Partners

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VIA – Email
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March, 25th, 2013
Karen Lipson
Director
Division of Policy
Office of Health Systems Management

Joan Cleary Miron, MPH
Director
Division of Primary Care Development
Office of Primary Care

RE: Stakeholder Letter Dated February 25, 2013

Dear Director Lipson and Director Cleary-Miron,

I would like the opportunity to address the concerns in Paragraph 9 of the "Stakeholder" letter dated February 25, 2013 as it relates to and from the perspective of "physician-based urgent care" ("PBUC") and share some background information with you about intra-Community Urgent Care as well.

Concerns outlined in Paragraph 9

Concern: ***Are urgent care providers or lack thereof, affecting quality, access, costs, disparities, patient satisfaction, or population health in "your" communities?***

In New York City's five boroughs PBUC will provide communities with access to qualified providers (Physicians/Mid-levels) for episodic and after-hours care. It will increase the ability to access this care by strategically locating the practices into the communities that currently do not have an urgent care option. The fundamental design of PBUC is to be inclusive and develop strategies that serve the needs of the community it plans to serve. We are in the process of obtaining case rate and fee for services urgent care contracts specifically targeting Medicaid Managed Care, Medicare and Private Insurance Plans that reflect our communities. Our pricing structure will be developed to promote not inhibit access. Our practice is making an investment on having a "state of the art facility" developed in the South Bronx recognizing that the community as all communities will have a "choice" so we will strive to provide not only a high level of patient care but also of patient service. We believe that given the costs and complexities in place at present with opening any medical practice and including PBUC will require the centers to address all of the concerns in the first bullet point.

PBUC will be positioned to treat that percentage of the population that is utilizing the emergency department for care that in not emergent. PBUC will also have the opportunity to identify at-risk patients who are not managing underlying or secondary/third conditions (disease) and provide a level or intervention and redirect these patients into more appropriate primary and specialized care.

Concern: ***Are urgent care providers affecting your organization or its members?***

Urgent care should be viewed as an accessory that compliments the existing stakeholders. Many urgent care centers do not participate in capitated plans that deliver primary care but instead offer an alternative setting to treat efficiently and economically episodic care needs. The demands on the health system over the next few years should allow the centers to be positioned to effectively support the stakeholders, serve the community and make an impact for the stakeholders and the patients. We have met with our community stakeholders and invested time to understand their needs and concerns in

order to develop a care "platform" that addresses each community's unique needs and maintain vital linkages in our communities between the stakeholders and residents. The response has been favorable and we are utilizing all of the available feedback to insure we make any adjustments to our platform.

Concern: ***Should New York State modify its approach to regulating these providers? If so how?***

At present we do not believe the State should modify its approach to regulating the provision of urgent care. We would like the opportunity to participate as a "stakeholder" in any process to determine how to better serve the needs of our communities and stakeholders.

intra-Community Urgent Care Background:

intra-Community Urgent Care (CUC) was formed to challenge current practices in the delivery system for episodic care. The initial driver is to target Medically Underserved Areas (MUAs) with high utilization of emergency department services. The average emergency department visit costs $1,400 and it is estimated that as high as 70% of Emergency Department (ED) visits could safely be seen at an alternative setting at a lower cost $100/$175 per visit. It is estimated that due in part from NYS Medicaid redesign and passage of the Affordable Care Act an additional 2.5 million New Yorkers will become Medicaid eligible and additional insured's will be placed into managed care.

Our goal is to provide a practical alternative to the emergency department with increased access for "episodic" care outside of the ED. The platform is inclusive and includes access and services to adults and children with behavioral and physical disabilities in their non-emergent medical needs and is sensitive to costs and cost containment related to care. CUC will focus on delivering the full spectrum of "urgent care" as defined by the Urgent Care Association of America.

If I can provide any further insight or if there is any opportunity to discuss this matter further please feel free to contact me [redacted]. Thank you.

Sincerely,

Raymond Miranti

Raymond Miranti
Administrator
Community Urgent Care PC
dba intra-Community Urgent Care
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[redacted]

March 25, 2013

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Joan Cleary Miron, Director
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Corning Tower
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RE: Physician Practices and Certificate of Need

Dear Ms. Lipson and Ms. Miron:

The volunteer members of the HealtheConnections Board of Directors and Health Planning Committee have reviewed and discussed the 'Stakeholder Letter' sent to us last month. They have concluded that we do not have enough information to truly answer the questions included therein. It may be appropriate for NYSDOH to arrange for a study of the issues.

We suggest the following principles to the Public Health and Health Planning Council:

- Less regulation is better than more.
- NYS should conform its regulations and policies to the Patient Protection and Affordable Care Act, and other federal guidance.
- Issues of access and capacity are best evaluated at the regional level.

If you have questions or wish to discuss these comments in greater detail, please do not hesitate to contact me at 315-472-8099 [redacted].

Sincerely,

Sara Wall Bollinger
Executive Director for Health Planning

American Congress Obstetricians & Gynecologists, District II
American College of Physicians, New York Chapter
Large Urology Group Practice Association
Medical Society of the State of New York
New York Chapter of the American College of Surgeons, Inc.
New York Section, American Urological Association
New York State Academy of Family Physicians
New York State Neurosurgical Society
New York State Psychiatric Association
New York State Society of Anesthesiologists, Inc.
New York State Society of Plastic Surgeons
New York State Society of Orthopaedic Surgeons
New York State Urological Society
New York Urology Trade Association
The Society of New York Office Based Surgical Facilities
The Upstate New York Oncology Hematology Society
Urgent Care Association of America

March 25, 2013

Karen Lipson
Director
Division of Policy
Office of Health Systems Management

Joan Cleary Miron, MPH
Director
Division of Primary Care Development
Office of Primary Care

NYS Department of Health
Empire State Plaza- Corning Tower
Albany, New York 12237

Dear Ms. Lipson and Ms. Cleary Miron,

Thank you for providing organized medicine and physician representatives with an opportunity to respond to questions included in your letter dated February 25, 2013. Through this document and follow up discussions, we hope to comprehensively inform the State's Public Health and Health Planning Council (PHHPC) regarding medicine's perspective on Certificate of Need (CON) Redesign and the impact of innovative physician practice models on health care cost, quality and access in New York State.

Certificate of Need

New York's Certificate of Need (CON) program was originally established at a time when hospitals were reimbursed based on the costs of their services. This reimbursement was structured prospectively and cost-based reimbursement encouraged hospitals to expand and develop excess service capacity. The CON process was established in order to control this expansion. Under CON regulation, the intended result was that new or improved facilities or equipment would be approved based only on a genuine need in a community.

There are many entities in this state and nationally, including the US Federal Trade Commission and Department of Justice, that have recognized the CON approval processes impede the delivery of high-quality care, and as such have supported the repeal of such laws. The FTC/DOJ testified:

> *"The Agencies' experience and expertise has taught us that CON laws impede the efficient performance of health care markets. By their very nature, CON laws create barriers to entry and expansion to the detriment of health care competition and consumers. They undercut consumer choice, stifle innovation and weaken the markets' ability to contain health care costs".*[i]

The FTC and DOJ believe that CON programs can pose serious competitive concerns that generally outweigh CON programs' purported economic benefit. Where CON programs are intended to control health care costs, there is considerable evidence that they can actually drive up prices by fostering regulatory barriers to entry, which by their nature are an impediment to health care competition. [ii]By protecting what are often high-cost providers, CON programs deny patients different, and possibly more affordable, higher quality treatment options or settings. The proponents of CON overstate the purported savings generated by CON programs by failing to offset alleged savings with the a number of significant costs incurred by both CON applicants and the Department during the course of the CON process. Fourteen other states have already repealed CON statutes, and most of the remaining CON states have greatly modified aspects of the programs to encourage more competition and innovation in delivery. Significant thought and consideration must be given to any future planning processes to ensure that private practice providers are not rendered at risk and financially vulnerable due to the significant market influences that current providers may bring to bear.

The undersigned believe that a process which examines CON Redesign must also consider the impact – both positive and negative- of a repeal of the CON process. Many changes occurring in the health care delivery system may make CON irrelevant in the future. Moreover, consideration should be given toward eliminating the application of CON for certain primary care facilities particularly given the need for increased primary care capacity and the movement away from fee-for-service reimbursement.

Clearly, the innovative approaches incentivized by the state and federal government in recent years have encouraged the formation of large, multi-specialty group practices, independent practice associations and physician hospital organizations, and have fostered integrated care delivery and payment and models such as the patient centered medical home or accountable care organization. Such models have enhanced care coordination and payment incentives to improve quality of care while reducing overall health system costs.[iii] CON should not be used by high-cost providers to discourage the formation of these integrated, physician-driven health delivery systems. Rather, New York public policy should support the further development of these and other innovative models.

For all of these reasons, the CON process should be considered for repeal or significantly modified so as to promote innovative and cost efficient practice models in New York State. New York State should

not expand or modify the criteria that define a diagnostic and treatment center under 10 NYCRR 600.8 to encompass any of these physician practice models.

Underpinnings of large, multi-specialty practices- impact on cost and quality of care
In today's healthcare delivery system, physician practices are finding it difficult to financially sustain given the reduced payment levels and increasing overhead costs. Physicians have few alternatives as free market forces and transparent fee for service suffered as insurer's payment practices and CON practices have been favored hospital networks to expand. In order to preserve the necessary doctor /patient relationship, physicians have had to explore other options. The large group is an attempt to maintain a high degree of autonomy while maintaining quality of care. Member physicians make up a group's governing body, which is headed up by a member-elected board of managers. Members must abide by the group's by-laws and the physicians in the group ensure a higher standard of care. Peer review processes in physician practice and group settings insures continued quality improvement.

Many of physician practices including group practices are invested in infrastructure and promise to provide clean electronic claims with the ability to accept e-remittance. Medicare electronic records and e-Prescribing initiatives have driven the development of these types of practice models. High costs associated with the acquisition of technology are best borne by consolidated practices. Physician practices including many large group and multi-specialty physicians are committed to investing in infrastructure, including those programs that promote meaningful use of EMR, preventive care and coordination of care with primary care specialties. Several have created a patient/physician portal which will ultimately allow data sharing of test results, and achieve administrative cost reduction between providers. Many participate in a data collaborative where various data analysis tools perform some of the most sophisticated quality data analyses available anywhere, and can benchmark against other members of the collaborative. They share quality improvement and best practices, thereby enhancing value by transforming data into actionable knowledge and accountable, evidence-based practice. As noted in *Trends and Changes in the New York State Health Care System: Implications for the CON Process* (UHF, 2012), 'groups with scale have the capacity to support organized quality improvement programs, staff development, and performance improvement processes, and they can employ systems to collect, analyze, and compare data on their providers' performance compared to that of their peers and to external benchmarks using evidence-based measures of quality and performance'.

A strong component of any physician owned practice model is their infrastructure which includes a comprehensive compliance program, which includes a Medical Management and Compliance Committee, and which upholds the patient as the first priority. Many have a comprehensive compliance program, which includes a Medical Management and Compliance Committee. Many practices hire a full-time compliance coordinator with a background in regulatory reporting requirements. These practices place a priority on full compliance with all applicable federal and state laws and regulations as well as coding rules and changes. They have formal and active Compliance Committees which meet monthly to perform internal chart reviews. Each physician is fully reviewed at least annually. These large practices also provide extensive educational outreach to physicians and staff. These steps, along with the implementation of an EMR system throughout the practice, help to ensure the integrity and accuracy of medical record documentation.

Many physician practices including large group and multi-specialty practices are NCQA Level II or Level III Patient Centered Medical Homes and are either driving or participating in the development of Medicare recognized Shared Savings Accountable Care Organizations in their communities. If they have office based surgical suites, they are accredited by one of the three recognized national

accrediting agencies (Accreditation Association for Ambulatory Health Care, American Association for Accreditation of Ambulatory Surgery Facilities, Inc. or The Joint Commission).[iv] If they have certain technologies in place, they are also accredited by other national accrediting entities. For example, Echocardiography labs are ICAEL (Intersocietal Commission for the Accreditation of Echocardiography Laboratories) Certified.

If CON requirements were extended to mega group practices the effect would be to stifle competition, reduce patient choices for care delivery and directly impact quality of care.

Impact on access, quality, and cost of care

Your letter dated February 25, 2013 also includes a number of questions concerning whether certain practice models affect access to care, quality of care, costs, patient satisfaction, disparities or population health and whether such practice models are affecting other organizations, presumably other health system stakeholders.

In response to this inquiry I direct your attention to the material submitted to you by various medical specialty societies and organizations including the NYS Society of Orthopaedic Surgeons, Society of New York Office Based Surgical Facilities, Urgent Care Association of America, Upstate New York Society of Medical Oncology and Hematology, New York Oncology Hematology and American College of Physicians, New York Section AUA, New York State Urological Society, New York Urological Trade Association, American Urological Association, American Association of Clinical Urologists and Large Urology Group Practice Association. Each organization has provided data and information relative to the inquiry, which in addition to this response, will be supplemented with additional studies as they become available. [v]

Urgent Care

Urgent Care Centers are walk-in ambulatory care centers, generally open seven (7) days each week often 13 or more hours each day. No appointment is required for a patient to receive care. These centers have a broad array of diagnostic and therapeutic services, often including x-ray, laboratory testing, on-site pharmacy, procedure rooms for laceration and fracture care, exam rooms, and specialized corporate services for employee health and workers compensation cases. Some of the most common conditions treated are fevers, upper respiratory infections, sprains and strains, lacerations, contusions, and back pain. Most centers also treat fractures, can provide IV fluids, and have x-ray and lab processing onsite. Centers are typically staffed with physicians, and may also have physician assistants, nurses, nurse practitioners, medical assistants and radiology technicians working with patients.

Urgent care centers are usually located in freestanding buildings, and the majority of centers are independently owned by physicians or groups of physicians. Approximately 25 percent are owned by a hospital or health system – and most of those are located off the main hospital campus. Physician owned urgent care centers are financed totally by the physicians who bear the financial burdens and risks.

It should be noted that urgent care centers are NOT freestanding emergency departments. They are not equipped to treat life-threatening emergencies, nor provide assistance for labor and delivery. Urgent care centers will refer patients to the emergency room if their condition is very serious.

Moreover, urgent care centers are NOT the same as in-store retail clinics. Urgent care centers treat a broader scope of services and ages (most retail clinics' minimum age is 18 months) than retail clinics, and have a different staffing model (primarily physicians vs. primarily NPs).

Urgent care centers are no different than other primary care medical practices such as general internal medicine and family practice and it is noted that these have never been subject to additional New York State DOH regulations or CON applications.

Office Based Surgery

Office-based physicians are a critical component of the healthcare system, fundamentally assuring the health of the community in which they practice. Office-based physicians include both doctors of medicine (MDs) and doctors of osteopathy (DOs) who are primarily engaged in the independent practice of medicine. These practitioners operate private or group practices in offices and clinics and are focused on providing care to their patients.

Studies have shown that with proper quality controls and recent technological advancements, outpatient surgery performed in accredited OBS facilities is as safe, if not safer than any other surgical setting, including hospitals and licensed Article 28 ambulatory surgical centers.[vi] Section 230-d of the Public Health Law which requires accreditation of office based practice at which surgery is performed has assured that surgery performed in OBS facilities meets the highest standards for patient safety. By separate letter, the NY Office Based Surgery Facilities (NYOBS) has provided data to support this contention. They have also supplied data which estimates that OBS facilities can achieve cost savings of between 30%-40% on the most common surgical procedures as compared with licensed Article 28 ambulatory surgical centers and hospitals.

Physician practices that provide advanced diagnostic imaging

In the original Report of the Public Health Planning Council on Redesigning Certificate of Need and Health Planning, Recommendation 8 expressed concern for the increased use of medical technologies and services and Recommendation 13 suggested that the criteria for imaging services in physician offices should be reviewed. These two elements of the report, which were included in the February 25th letter, have a lot of implications for the day-to-day operation of physician practices in NY and, if changed, have a significant impact on the manner in which patient care is provided.

Advances in medicine have resulted in more injuries and diseases being discoverable through imaging studies as the technology has improved. For example, MRI is the most accurate means by which to assess AVN, occult fracture in native hips. It is recommended by the FDA for assessment of ALTR around implants and it has been demonstrated to be the most accurate means by which to assess component loosening. New advances in imaging also enhance the ability to accurately assess articular cartilage which continually drives disease management (ie: “R/O meniscal tear” is often a chondral shear, requiring cartilage restoration techniques that have a markedly different rehab than simple meniscectomy). Additionally, many patients referred for “R/O labral tear” are found to actually have sacroiliitis and delays in imaging substantially delays institution of appropriate treatment for the inflammatory condition, sometimes with devastating results.

Medical science requires a commitment from physicians and patients to continue to work on advancing studies. Oftentimes these advances require the use of imaging studies. Any restriction that may be imposed by the State of New York on imaging services should be carefully evaluated.

Physician practices that provide radiation therapy

Radiation therapy represents an important component of cancer treatment, one part of the triad that includes surgery as well as chemotherapy. Historically, these capital intensive services were delivered nearly exclusively in the hospital setting; however, national trends indicate that an increasing number of patients are seeking care in the physician office setting. Of note is that this

trend preceded the integration of radiation oncology services into large group practice – these non-hospital services were being performed at free-standing radiation oncology facilities generally owned and operated by independent radiation oncologists.

Incorporation of radiation oncology services into group practices on a more substantive scale began in the latter half of the last decade with the development of large integrated urology group practices. Proponents of these arrangements argue that integration of medical services facilitates the development of coordinated clinical pathways, improves communication between specialists, offers better quality control of ancillary services, and enhances data collection, all of which can improve patient care and maximizes economic efficiencies.

Physician practices providing advanced diagnostic imaging and radiation therapy

In the February 25th letter, stakeholders were asked about how access to care, quality of care, patient satisfaction, costs, population health, and other aspects of how advanced diagnostic imaging and radiation therapy in the physician office setting have affected them, and whether or not the state should expand or modify the criteria that define a diagnostic and treatment center under 10NYCRR 600.8 to encompass any of the physician practice models. Integrated community cancer practices are in a unique position to answer these questions collectively, and to testify as to the severe implications for the day-to-day operation of physician practices in NY should an expansion or modification of the criteria that define a diagnostic and treatment center include physician practice models. In short, it would be particularly disruptive for the care of cancer patients overall.

Americans enjoy the world's best cancer care[vii], the core of which is integrated community oncology—surgical medical oncologists and radiation oncologists practicing or working together, as a team, in physician-owned, community-based cancer centers. Nearly 80% of all US cancer patients receive their care in the community setting, where the most advanced, highest-quality, and lowest-cost cancer care is brought together by community-based oncologists. Community cancer care is not only the most preferred site of care by patients, but it is also demonstrably the most cost-effective[viii]. And it is the integrated model of care—one that includes the entire continuum of care (radiation therapy, chemotherapy, surgery, diagnostic imaging, clinical trials, etc.) together close to where patients live and work—that is why the community setting has proliferated and resulting patient outcomes have improved.

With community-based cancer care being the most cost-effective setting in which cancer patients can be treated while maintaining equivalent health outcomes,[ix] the federally established ability for physicians to assemble ancillary services—principally, with regard to this discussion, advanced medical imaging and radiation therapy—has been crucial to this advancement in the effective and convenient delivery of cancer care.

According to a recent analysis of American Cancer Society data, medical imaging technologies—such as computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET)—contribute to America's continually declining cancer mortality rates.[x] In particular, death rates continue to decline for lung, colorectal, breast and prostate cancers. The ability of cancer patients to access these diagnostic services at physician practices close to home, as part of an integrated cancer care team, has increased greatly over the past decade—at the same time that improvements in cancer survivorship have increased. And the quality assurance and patient safety standards for these imaging services in the physician office setting is second to none, with facilities fully accredited by the American College of Radiology (ACR), as is required by Medicare.

A separate recent report showed that radiation therapy treatment episodes lasting 1 and 2 months and were provided to cancer patients in the physician office setting were between 7% and 17% less expensive respectively than similar hospital outpatient-managed episodes of radiation therapy.[xi] And as with the imaging services, many radiation oncology services provided in the physician office setting meet the highest accreditation standards as established by the ACR. This is done to ensure: 1) they meet nationally accepted standards of care; 2) they have personnel well qualified through education and certification to administer radiation therapy; and 3) their equipment is appropriate for the prescribed treatment regimen. ACR accreditation standards have been established to guarantee patient safety and treatment quality.

Meanwhile, it must be noted that reimbursements for the same radiation therapy services provided to similarly situated patients at different sites of care vary widely in Medicare's payment system, where Medicare is the largest insurer by far in covering cancer patients. Based on the 2013 proposed physician fee schedule for CY 2013 there exists a substantial disconnect between payments for radiation oncology services in community-based and hospital-based settings, with hospital outpatient department payments about 25% higher overall and a significantly higher percentage differential for intensity modulated radiation therapy (IMRT) and stereotactic body radiation therapy (SBRT), 70% and 188% respectively. Yet despite an unequal reimbursement playing field, the physicians practicing in community oncology—those providing coordinated cancer care in this setting—continue to provide patients with equivalent health outcomes at significantly lower costs to both patients and payers.

In a separate letter, the Upstate New York Society of Medical Oncology & Hematology and New York Oncology Hematology will provide additional data to support the above statements. They will also supply data estimating that community oncology can provide meaningful savings over the same services provided in licensed Article 28 centers and hospitals, across many cancer diagnosis groups.

Corporate Practice of Medicine Doctrine

Your letter inquires as to whether the 'mega' physician practice model violates the spirit of the corporate practice of medicine doctrine. The corporate practice of medicine doctrine is based upon the public policy consideration to prevent corporate interference in the practice of medicine. Most states have a corporate practice of medicine doctrine. The corporate practice of medicine doctrine is based on the concern that corporate control of licensed physicians would interfere in a physician's exercise of independent medical judgment in the best interests of the patient and cause intrusion into the practice of medicine by corporate entities that are not licensed to practice medicine and therefore not subjected to the same professional standards or regulatory control as licensed physicians. In New York there are a number of exceptions to the rule, For example, a medical school may hire physicians and treat patients as part of its mission to promote medical science and instruction.[xii]School health programs constitute another exception to the CPM bar.[xiii] In addition, hospitals in New York may employ physicians to render medical services to the hospital's patients without violating the CPM prohibition.[xiv]

Article 15 of the Business Corporation Law (BCL) was enacted with the corporate practice of medicine doctrine in mind, and ensures that professional corporations may only be owned and controlled by licensed health professionals. Article 15 of the BCL permits the practice of medicine through a professional corporation. Section 1507 of the BCL states that shares in a BCL may only be issued to an individual who is authorized by law to practice the profession which such corporation is authorized to practice. Section 1508 of the BCL states that no person may be a director or officer of a professional corporation unless he is authorized by law to practice the profession which such corporation is authorized to practice and is either a shareholder of such corporation or engaged in the practice of his profession in such corporation.

In addition, Section 1204 of the Limited Liability Company law provides that a member of a professional service limited liability company (PLLC) must be a professional authorized by law to practice the profession that such limited liability company is authorized to practice. With respect to a professional service limited liability company formed to provide medical services, each member of such limited liability company must be licensed pursuant to Article 131 of the Education law to practice medicine.

Therefore, the enactment of legislation to permit the practice of medicine through a professional corporation or professional service limited liability company is consistent with the corporate practice of medicine because it requires that these entities can only be owned and controlled by licensed professionals who are licensed and qualified to practice the profession that the entity is authorized to practice.

The purpose of the corporate practice of medicine doctrine is to ensure that the practice of medicine is controlled by licensed physicians, and not subject to control or intrusion by non-physicians. The corporate practice of medicine doctrine requires physician ownership and control—but does not dictate the "size" of the medical practice. Accordingly, these statutes do not limit the size of the PC or PLLC in terms of number of physician shareholders/members, or in terms of financial resources. Increasingly, physicians are finding it difficult to practice as a solo or small group doctors and are becoming salaried employees of hospitals or large group medical practices. This is due to many factors—but, among the factors driving doctors to join either hospitals or large groups is the growing complexity of operating a medical practice; reduced reimbursement; costs of operating a medical practice; professional liability insurance coverage costs; costs of EHR and other necessary medical equipment.

Large and multi-specialty medical practices are vitally necessary to the community and to the patients served by such practices. Financial and clinical integration enables enhanced care coordination and improved quality of care at a much more efficient price point than care received in hospital care settings. Large group practices are needed in order to preserve choice and access. Otherwise, the practice of medicine will be controlled by hospital systems—which is contrary to the corporate practice of medicine doctrine.

As mentioned above, the practice of medicine through faculty practice plans is recognized by the common law; see Albany Medical College v. McShane 104 A.D. 2d 119, 481 N.Y.S. 2d 917 (3d Dept. 1984); affirmed 66 N.Y. 2d 982, 499 N.Y.S. 2d 376 (NYS Ct of Appeals, 1985). This is codified in Education law 6531, which permits practice through a university faculty practice corporation.

Even when hospitals are allowed to employ physicians, they are prohibited from owning professional corporations, whose shares are restricted to licensed professionals. Instead, they execute contractual arrangements with physicians under what is known as the captive professional corporation model. In a captive PC model, the PC issues all of its stock to a single or group of physician shareholders who is/are also attending at the hospital. The structural and operational control over the PC, its shareholders and directors is conveyed to the hospital which can include an administrative services agreement between the hospital and the PC. A stock transfer restriction agreement pursuant to which the physician shareholder(s) is/are prohibited from transferring their shares to another physician without prior approval of the hospital assures the hospital is protected. The hospital's governing body is obligated to evaluate the care and treatment of patients and based on these evaluations assure that noted problems are addressed. Thus, from a patient care perspective, the role of a hospital's governing body concerning the medical staff isn't different from the role of the hospital with a captive

professional corporation and its physician shareholder(s). Moreover, since they are both licensed providers seeking to deliver high quality patient care, it is difficult to comprehend how such a relationship runs afoul of the corporate practice doctrine's protection of the physician- patient relationship and corporate intrusion into medical decision-making.

The corporate practice of medicine doctrine ensures that medical practices should be owned and controlled by physicians—and not subject to lay intrusion, The purpose of the doctrine is to ensure that physicians control medical practices. It has not been viewed as a means by which to limit the size of physician controlled practices. Larger medical group practices are necessary because increasingly physicians are finding it economically difficult to continue to practice in the form of a solo or small group. Larger or multi-specialty group practices provide a cost efficient, coordinated care setting through which health care can be delivered. If the corporate practice of medicine doctrine is used to deter the development of such practice settings, a greater concentration of control of the practice of medicine will rest in the hands of a relatively few large hospital chains.

We believe that medical decision-making should remain the exclusive province of licensed physicians, and not business managers. Mega-practices and other new service delivery vehicles must be actively controlled by physicians who are not mere figureheads for corporate investors and managers. To assure this, we encourage the Departments of Health and Education and other state agencies to enforce the corporate practice prohibition now in statute.

Community Technology Assessment Advisory Board

The Community Technology Assessment Advisory Board (CTAAB) was established in 1993 to augment the health care planning process in the Rochester area and to continue the Rochester community's legacy of high quality, affordable health care. The CTAAB is an independent board that: (1) reviews selected issues such as new or expanded technology, new or expanded services, and capital expenditures; (2) makes judgments on these issues; and (3) communicates its decisions to the health care community. CTAAB advisory board decisions are not binding on health insurers.

You have asked for our comment on the effectiveness or value of this type of process and whether such a process would be appropriate for other regions of the state. Our first observation is that each region of the state is different with different stakeholders and needs. The CTAAB should not be viewed to be a one size fits all approach. Moreover, this model should not be used to replicate a duplicative CON process on a community basis given the complexity of review which would be necessary. Nor should such a community based process be used to determine whether and to what extent large group physician practices should be allowed in a community.

Conclusion

In conclusion, we thank you for your inquiry and we look forward to meeting with you to discuss these very important matters. We respectfully oppose the creation or extension of additional regulatory burdens on private physician practices and recommend consideration of other ways to enable market forces to operate to assure the delivery of cost efficient, high quality care throughout the healthcare system.

Sincerely,

Robert Hughes, MD
President
Medical Society of the State of New York

Terence M. Brady, MD, FACP
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American College of Physicians, New York Chapter

Deepak A. Kapoor M.D.
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Michael L. Parks, MD
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The Society of New York Office Based Surgical Facilities

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Marc Salzberg, MD
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Frederick A. Gulmi, MD
President
New York Section, American Urological Association

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[i] Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform (September 2008).

[ii] Id.

[iii] SC Gleason, A Comparison of Quality and Utilization Problems in Large and Small Group Practices, *Physician Executive*, 21 (1995) 29-33.

[iv] NYS Public Health Law §230-d.

[v] See Letters from: New York State Society of Orthopaedic Surgeons, March 22, 2013; Large Urology Group Practice Association, Society of New York Office Based Surgical Facilities, March 12, 2013; Urgent Care Association of America, March 20, 2013; American College of Physicians, NYS Radiological Society .

[vi] MS Clayman, Promoting a Culture of Patient Safety: A Review of the Florida Moratoria: What We Have Learned in Six Years and the Need for Continued Patient Education, Annals of Plastic Surgery, 58(3), 2007,:228-91; G Bitar, Safety and Efficacy of Office-Based Surgery With Monitored Anesthesia Care/Sedation in 4,778 Consecutive Plastic Surgery Procedures, Plastic & Reconstructive Surgery, 111(1), (2003) 150-6; and RE Iverson, Patient Safety in Office-Based Surgery Facilities: I. Procedures in the Office-Based Surgery Setting, Plastic & Reconstructive Surgery, 110(5), 2002, 1337-42.

[vii] http://www.ncpa.org/pub/ba649

[viii] Avalere Client Report: Total Cost of Cancer Care Site of Service. March 2012. http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf

[ix] Milliman Client Report: Site of Service Cost Differences For Medicare Patients Receiving Chemotherapy. October 19, 2011. Kate Fitch and Bruce Pyenson. http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf

[x] http://www.medicalimaging.org/2013/01/17/new-american-cancer-society-report-shows-medical-imaging-technologies-contribute-to-declining-u-s-cancer-death-rate/

[xi] Avalere Client Report: Total Cost of Cancer Care Site of Service. March 2012. http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf

[xii] Albany Med. Coll. V. McShane, 104 A.D. 2d 119 (N.Y. App. Div. 1984); *aff'd*489 N.E. 2d 1278 (N.Y, 1985).

[xiii] N.Y. Educ. Law Sec.901 *et seq.*

[xiv] People v. John H. Woodbury Dermatological Instit., 192 N.Y. 454 (N. Y. 1908)

PRIMARY CARE DEVELOPMENT CORPORATION

www.pcdc.org

Dear Joan and Karen,

We would very much like to be responsive to your March 25, 2013 letter seeking comments on CON reform for different types of ambulatory care providers. While we cannot respond specifically to many of the questions (as we are not a direct service provider organization) we are quite interested in the subject. At this point, we need to become more informed about the issues, but we do think that, in general, the regulatory framework should focus more on cost, quality and access rather than different types and configurations of providers. To that end, we do believe that there is a regulatory role to ensure that communities have strong, stable, and integrated primary care in their communities, and efforts to promote that, and prevent destabilization, are laudable. I think our comments (attached) on regional planning and removal of CON for Article 28 primary care facilities holds some relevance to this discussion as well.

We look forward to participating in this important discussion as it moves forward.

Dan Lowenstein
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PRIMARY CARE DEVELOPMENT CORPORATION

www.pcdc.org

To: New York State Public Health and Health Planning Council

From: Ronda Kotelchuck, CEO and Dan Lowenstein, Director of Public Affairs, Primary Care Development Corporation

Date: December 5, 2012

Re: Comments on PHHPC Health Planning Committee Certificate of Need and Regional Health Planning recommendations

The Primary Care Development Corporation (PCDC) provides the following comments regarding the Certificate of Need (CON) and regional planning recommendations developed by the Public Health and Health Planning Council Health Planning Committee.

We commend the committee and the NYS Department of Health staff for undertaking this critical and forward-looking effort. As a whole, these recommendations form a framework on which to build state and regional health policy that responds effectively to potentially dramatic changes in our health care payment, delivery and investment environment. The recommendations encourage the health care system to be more responsive to the Triple Aim of better patient experience, healthier populations, and lower per capita costs.

While we reserve judgment on most of the specific recommendations, PCDC would like to provide comments on elements that impact primary care directly.

1. Advancing the Triple Aim through Regional Planning

We support the Committee's recommendations 1 through 5 which concern development of a regional planning infrastructure in New York State, including the establishment of Regional Health Improvement Collaboratives (RHICs) in 11 region throughout New York State. As indicated in the recommendations, RHICs should be neutral, multi-stakeholder entities whose mission is to advance on a regional level state health reform efforts to achieve the Triple Aim.

RHICs could bring back a health planning infrastructure that has long been missing from New York State. This would help us make more informed decisions about health care resources and give New York State residents greater control over the health of their communities. RHICs would aid the NYS Department of Health in implementation of State health policy related to public health and facilities planning; build capacity through knowledge and data sharing; and form significant partnerships with community stakeholders. This could be particularly important to helping us understand the regional impact of new payment and delivery models like health homes and accountable care organizations.

In terms of governance, RHICs need to be stable and enduring. One of the key questions that needs to be answered before a governance structure can be discussed is how much and what kind of authority RHICs should have, and what should the relationship be with the NYS Department of Health? The RHICs should act in partnership with local health and service providers and other stakeholders (e.g. consumers, businesses, community health centers, behavioral health providers, local health departments, hospitals,

health plans, research organizations), but should not be dominated by any stakeholder or type of stakeholder.

Establishing functioning RHICs should be a top priority, as the infrastructure could play a vital role in New York may soon have the opportunity to deploy hundreds of millions of dollars each year over five years for health system redesign under the MRT waiver. It will be vitally important that we have a regional health planning infrastructure to help us use these funds effectively and ensure their impact is well documented.

2. Elimination of Certificate of Need (CON) for primary care facilities, whether D&TC or hospital extension centers

PCDC supports this recommendation. With 2.3 million New York State residents lacking sufficient primary care access, New York has a major primary care shortage that will only intensify as hundreds of thousands of newly insured individuals seek primary health care services. New York State should do everything possible to increase supply of quality primary care. Indeed, this is a major objective of New York's MRT waiver request, which provides substantial capital, workforce training and technical assistance funding to expand access to primary care.

The recommendation recognizes that new payment models are increasingly incentivizing quality primary care. Primary care provider would still be required to obtain a license, which includes character and competence review, quality of care delivered, and meeting facility construction standards.

The CON requirement has been problematic for some time now. First, while CON could assess primary care need, it has primarily been used as tool to guard against oversupply of medical services. There is so much unmet primary care need that the CON process becomes a barrier to increasing supply. Second, CON applies to D&TCs and hospitals, but not private practices, the rationale being that Article 28 facilities received higher Medicaid reimbursements than private practices.

But a blurring between traditional safety net providers and new entrants is beginning. Starting in 2013, physicians will be reimbursed at higher Medicare rates for Medicaid visits. Managed care plans are beginning to pay more (sometimes substantially more) for high quality primary care that prevents the need for higher cost interventions. This is attracting new provider types into low income communities who see value in providing high quality primary care services, but who would not be covered by CON. It is only fair that the playing field be leveled, and providers be judged on the quality and value of care they provide.

This is not to say that New York State should abandon oversight of primary care. But the instruments to measure supply, demand, quality and value of primary care are quite different from those employed through the CON process. Indeed, certification of Accountable Care Organizations could serve as an alternate means to promote appropriate distribution of facilities and services; better data collection will enable identification of high-need areas; and RHICs can play a critical role in assessing both the quality and quantity of primary care services in low income communities. While an appropriate methodology has yet to be developed, we believe New York has the tools to do so.

3. Conclusion

The dynamic evolution of health care today is incredibly promising yet fraught with risk and uncertainty. New payment and delivery models may correct for some of the market distortions brought about by traditional fee-for-service, but traditional market dynamics alone will still not be sufficient for health planning, particularly in underserved communities with large health care service gaps.

We commend the PHHPC Health Planning Committee for developing a planning and regulatory framework that anticipates changes in our health care system and responds accordingly. We recognize that this is a first step in a long process, but it is critically important to helping New York transform its healthcare delivery system into one that is more responsive to the needs of patients, produces better health outcomes, and reduces the cost burden on families, businesses and New York State.

About the Primary Care Development Corporation (PCDC)

PCDC (**www.pcdc.org**) is a nonprofit organization dedicated to transforming and expanding primary care in underserved communities to improve health outcomes, reduce healthcare costs and disparities. PCDC's programs enhance access to primary care through flexible financing to build and modernize facilities; coaching and training to strengthen care delivery; and policy and advocacy initiatives that support and sustain primary care. Since 1993, PCDC has partnered with nearly 900 primary care organizations throughout the U.S. to adopt a patient-centered model of care that maximizes patient access, meaningful use of health IT, care coordination and patient experience, and emergency planning. Certified as a Community Development Financial Institution (CDFI) by the U.S. Treasury, PCDC has financed 100 primary care projects valued at $415 million, creating primary care access for more than 900,000 patients in New York State. This investment has improved 840,000 square feet of space and created or preserved more than 4,600 jobs in low-income communities.

Family Planning Advocates
of New York State

Karen Lipson
Director, Division of Policy
Office of Health Systems Management

Joan Cleary Miron
Director, Division of Primary Care Development
Office of Primary Care

March 28, 2012

Dear Ms. Lipson and Ms. Miron;

Thank you for seeking FPA's input on the emerging issue of enhanced physician practices. As you are aware, Family Planning Advocates of New York State ("FPA"), represents the state's family planning provider network in New York. Our provider members include the state's Planned Parenthood affiliates, hospital-based and freestanding family planning centers, and a wide range of health, community and social service organizations that collectively represent an integral part of New York's health care safety net for uninsured and underinsured women and men. Family planning centers provide critical, but a limited range of primary care services such as family planning care and counseling, contraception, pregnancy testing, prenatal and postpartum care, health education, abortion, treatment and counseling for sexually transmitted infections, HIV testing and prevention counseling as well as breast and cervical cancer screenings.

As the health care delivery system and payment methodologies change, we are concerned about preserving this model of health care delivery, as it is both an effective way to provide sensitive reproductive health services as well as reflective of New York policy and how women and to a lesser extent, men, prefer to obtain such services. The free access policy, which allows women in the Medicaid program to access reproductive health services from any provider that accepts Medicaid, reflects the reality that many women prefer to seek reproductive health services from either a family planning health center or an OB/GYN practice. Similarly, New York insurance law allows women insured through private, commercial plans to obtain reproductive health services without a referral from their primary care provider. For many young women, family planning centers are their only source of health care, as reproductive health care is their most pressing health care need. More than 6 in 10 women who receive care at a family planning center consider it their primary source of care. Many patients seek services this way because of family planning providers' commitment to providing confidential care, our expertise in providing counseling and education on reproductive and sexuality-related topics, and our ability to schedule patients on a timely basis. Family planning providers are also

expert at the provision of long-acting reversible contraceptives—such as the IUD—which are more effective than other methods of contraception. When a patient needs contraception or testing and treatment for an STI, a several week wait to be seen does not meet patient needs; family planning providers maintain schedules that allow patients to be seen without a long delay in scheduling.

We are very concerned that family planning providers' model of health care delivery could be threatened by emerging trends in delivery. Currently, we are most concerned about a growing focus on providing enhanced payments and other incentives to providers that offer a more comprehensive range of services than those offered by family planning providers. However, we can certainly offer some insight into how the emerging trend of enhanced physician practices could affect family planning providers.

Questions 1 through 3

At this point in time, it is hard to point to any adverse impacts from the types of enhanced practices (faculty practice plans, captive and independent practices and urgent care providers) you mention in numbers one through three in your request for comments. However, that does not mean we do not see the potential for impacts on our delivery model in the future.

An increase in provider groups that do not accept Medicaid has the potential of perpetuating disparities. With an increase in privately insured individuals that will occur with full implementation of the Affordable Care Act, we fully expect to see shifts in how patients access health care and anticipate changes in patient mix. If the growth of enhanced physician practices results in a decreased number of providers accepting Medicaid, family planning providers could see an increase in the number of patients who are uninsured or insured by the Medicaid program and a decrease in the mix of privately insured patients. The financial impact of this is uncertain, but there is the potential that the uninsured and Medicaid populations will be further marginalized, particularly if Medicaid managed care plan rates do not meet the costs of providing care—something that is of paramount concern to many of our providers. This would be a particular problem if family planning providers are not included in the networks of private insurance plans as it would cause further stratification in how insured and uninsured people seek care.

Our one concern about urgent care, mentioned in question 3, is that urgent care centers may see patients in need of emergency contraception or they may diagnose pregnancy. Without any quality data, it is difficult to know if women are receiving necessary information and referrals.

Questions 4 through 6

We feel that the types of practices mentioned in questions four through six (practices that offer office-based surgery, diagnostic imaging and radiation therapy), for the most part, do not offer the same mix of services as provided at family planning centers, so we do not see impacts. Family planning providers do, however, refer patients for mammograms and other diagnostic tests when indicated. It will continue to

be important that patients are able to access providers that accept Medicaid and/or grant funding to pay for these services.

Questions 7 and 8

Although it is still too premature to be able to predict with any certainty the impacts the changing nature of physician practices will have on the family planning model of care, holding private entities and regulated providers to different oversight standards could lead to adverse financial impacts on providers.

FPA recognizes the value of regulating health care providers. We strongly believe that complying with Article 28 requirements and the commensurate oversight ensures that care provided meets patient needs, adheres to professional standards of care and is offered in facilities designed to ensure patient safety. Adhering to Article 28 standards has associated costs which are currently reflected in clinic rates. Although some enhanced practices may be located in facilities that meet similar construction standards, they do not have the same costs of compliance as providers licensed under Article 28. It is essential that this enhanced rate be maintained whether or not the State determines there should be more oversight of enhanced practices.

We do see one potential benefit to keeping enhanced practices out of the Article 28 regulatory scope and that is the seeming ability that 10 NYCRR 703.6 gives to providers regulated under Article 28 to open a part time clinic at the site of a private medical practice. This is a potential model of co-location that several family planning providers are currently exploring, although none to date are ready to make a concrete proposal.

10 NYCRR 703.6(3) states that:
A part-time clinic also shall not be located in space which is part of another facility licensed under Article 28 of the Public Health Law, unless such part-time clinic is operated as part of an approved State Department of Health public health initiative, or in space which is part of the private office of a health care practitioner or group of practitioners licensed by the State Education Department.

Given the reluctance of CMS to allow co-location between licensed entities, we see this as one potential cost-effective way of expanding services to new locations.

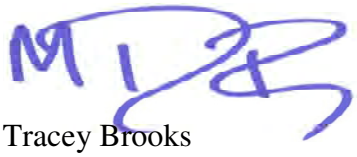
Question 9

In regard to question nine, we do not feel that urgent care centers or free-standing emergency departments offer comparable services, so we do not at this point see an impact on family planning providers. We do have some minor concerns about retail clinics as some do offer pregnancy testing and emergency contraception. At this point, our concerns surround quality and a lack of data that would show this type of setting can adequately meet patient needs for continuity of care and serve as an entry to primary health care as we see in family planning centers.

Question 10
FPA is not familiar with the Community Technology Assessment Advisory Board in Rochester so we cannot provide specific comments about its work and whether it is a model that should be replicated.

We look forward to discussing these concerns with you,

Sincerely,



Tracey Brooks
President and CEO

Suburban Hospital ALLIANCE OF NEW YORK STATE, LLC
Representing the shared advocacy interests of the
Nassau-Suffolk Hospital Council (NSHC) and the Northern Metropolitan Hospital Association (NorMet)

April 8, 2013
Via E-mail: phhpcplanning@health.state.ny.us

Ms. Karen Lipson
Director
Division of Policy,
Office of Health Systems Management
NYS Department of Health

Ms. Joan Cleary Miron, MPH
Director
Division of Primary Care Development
Office of Primary Care
NYS Department of Health

Dear Ms. Lipson and Ms. Cleary Miron:

Thank you for the opportunity to provide input related to the considerations of the State's Public Health and Health Planning Council (PHHPC) pertaining to the oversight of physician practices.

Rather than addressing individual situations posited under each major query in the request for comment, we are proposing strategies that may be useful in adapting current oversight and regulation to best address the wide variety of environments around the state. We also anticipate that these proposed strategies will support attaining the goal of reinvesting to build a more robust healthcare delivery system that more effectively meets the needs of New Yorkers.

There exists a global need to level the playing field between physician practices and hospital services in order to best serve patients.

Reducing the need for burdensome, costly CON applications that are required of hospitals but not of physician groups will help level the playing field. Reducing CON will accelerate hospitals' ability to transform into the more flexible systems required for healthcare system reform. As acknowledged in your February 25 letter, "Although they [physician practices] provide increasingly complex and costly services, these practices operate with far less regulatory oversight. . .than licensed health care facilities."[1]

Specifically, CON requirements of hospitals should be immediately brought into line with those less cumbersome requirements of the physician practices for the same and similar clinical services. We recommend eliminating the CON requirement for hospitals on any service that can be provided by a non-Article 28-licensed provider. For example, private physicians seeking to partner with the hospitals in their region should not face onerous structural requirements imposed on the hospital sector, which can inflate costs for developing new primary care capacity several-fold. As long as healthcare professionals are qualified, the ability to provide *services* should not be impeded by the structure in which the service is provided.

Another example is that hospitals should not need to file a CON for construction to relocate and/or update an existing clinical service line.

Services with the Highest Technology Should Still Be Regulated – Across Settings
Due to the significant expenditure to obtain highly technologic equipment and provide the services, and overutilization that occurs when there is excess capacity, we encourage egalitarian regulatory oversight across practice settings of the highest healthcare technology. This will also help meet one of the original, laudatory objectives of CON: to protect the safety of patients and their access to care.

Flaws in the Current CON Process Related to Assessment of Community Need in High Tech Service Lines Should Be Corrected. There are three significant issues that we believe the Committee should consider in its deliberations surrounding assessment of community need.[2]

- First, it is almost impossible for the DOH to correctly assess capacity of resources when it does not have legal oversight or routine access to the practices. However, just because it cannot be quantified does not mean that the resources do not exist. As demonstrated by the Northern Metropolitan Hospital Association during the CON review of the Memorial Sloan Kettering application, there was not only no *shortage* of capacity, but in fact – *without* the Harrison facility – there was *excess* capacity for linear accelerators in Westchester County. Yet, this did not impact the approval.
- Second, historically, the Council has disregarded whether residents of a particular area had access to services. Referring to the MSK CON example, the Westchester County residents already had access to a full-range of quality oncologic care – both at hospitals and private provider practices within the County and many more facilities and practices in nearby counties.
- Third, when new facilities arise in an already well-serviced market, the new facilities cause significant disruption and sometimes even irreparable damage to the existing health care delivery system.

In summary, a leveling of the regulatory field over hospitals and physician practices needs to occur to foster more rapid and cost effective offering of clinical services, bringing hospital requirements into line with the less restrictive establishment requirements of physician practices. I am available for further discussion and appreciate the opportunity to comment. Thank you for your consideration.

Sincerely,

Kevin W. Dahill

Kevin W. Dahill
President & CEO

SOURCES

1. February 25, 2013 Letter from NYS DOH Directors Karen Lipson and Joan Cleary Miron.
2. PHHPC Testimony of Kevin Dahill: September 2011.

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COMMENTS BY THE HEALTH LAW SECTION

Health #1 April 8, 2013

On behalf of the Health Law Section of the New York State Bar Association, we thank you for the opportunity to submit comments in response to the February 25, 2013 letter of Karen Lipson and Joan Cleary Miron.

1. ***Question:*** Should New York State expand or modify the criteria that define a DTC under 10 NYCRR § 600.8?

   Answer: Yes, New York State should modify the criteria in § 600.8 for the reasons that follow.

   We note, as a preliminary matter, that the licensure and regulation of physicians engaged in the private practice of medicine, whether in small groups or in complex multi-specialty mega-practices, is the purview of the Department of Education, not the Department of Health.[1] Thus, any attempt by the Department of Health ("DOH") or the Public Health and Health Planning Council ("PHHPC") to amend Title 10 of the NYCRR in order to bring any type of physician practice under the regulation of the Department of Health as a diagnostic and treatment center, and to subject it to Certificate of Need approval, would likely not survive the expected legal challenges to such an administrative action. We believe legislation would be necessary. See, e.g., *Boreali v. Axelrod,* 71 NY2d 1 (1987).[2]

[1] The PHHPC appears to be aware of this issue, since it states the following in an appendix to its recently adopted report on redesigning the CON process: "Notably, private physician practices are generally not covered by CON," citing to *Clifton Springs Sanitarium Co, Inc v. Axelrod*, 115 A.D.2d 949 (1985). *See* PHHPC Report on Redesigning Certificate of Need and Health Planning adopted on 12/6/2012 at Appendix F, fn 2. Leave to appeal was denied, 67 N.Y.2d 609, 494 N.E.2d 114, 1986 N.Y. LEXIS 18174, 502 N.Y.S.2d 1028 (1986).

[2] In this connection, legislation was advanced by Governor Mario Cuomo in the early 1980s seeking to subject the acquisition of certain imaging equipment (such as CAT and MRI equipment) to CON review. That legislation was never enacted. The failure to enact that legislation could be used to support an argument that DOH lacks authority now to require a CON. Indeed, the court in *Clifton Springs* notes that "efforts in recent years to bring privately owned equipment used on hospital inpatients within the State's CON requirements have consistently failed to obtain legislative approval."

The purpose of § 600.8 is to define what constitutes a "facility or institution engaged principally in providing services by or under the supervision of a physician…" pursuant to Public Health Law § 2801(1) and to distinguish such a facility from the operation of a physician office. The former is subject to licensure and CON review by DOH, and the latter is not.

- The criteria currently listed in § 600.8 fail adequately to distinguish between the operation of a facility and the private practice of medicine. The current criteria are both over- and under- exclusive, and are outmoded. Examples follow:
    - § 600.8(a) only mentions one legal way to organize a group practice, as a professional service corporation ("PC"), and fails to mention other ways now legal under New York law, including as a professional limited liability company ("PLLC") or a university faculty practice corporation ("UFPC") organized under section 1412 of the Not-For-Profit Corporation Law.
    - § 600.8(c)(1) and (c)(4)(ii) and (v): In a large, muli-specialty group, a primary care physician may refer a patient for laboratory or radiology services to "another location" not in his office.
    - § 600.8(c)(3): In a large physician practice, the practice may allow "after hours" services, where a patient may end up seeing a physician that the group practice has assigned to see all patients of the group practice after regular office hours.
    - § 600.8(c)(4)(iii): In this day and age, a physician group practice often "insures adherence to standards" such as quality standards and other standards required by third party payors such as Medicare and MCOs.
    - § 600.8(c)(5):
        - Physician group practices enter into managed care contracts that require the group to determine the amounts to be billed. Payments generally are made to the group, not to the individual physician.
        - Given HIPAA requirements and laws and regulations governing electronic medical records, the group is responsible for maintaining medical records and patient charts.
        - Income distribution is a function of the partnership agreement, PLLC operating agreement or employment contract between the group and the physician.
    - The criteria fail to consider *control* by non-physicians through financing, administration, and management.

- The Department of Health ("DOH") does not actively enforce the provisions of the current regulation. Having regulations that the state does not enforce undermines respect for the law. It also makes it difficult for attorneys to advise clients on properly structuring arrangements.

- Moreover, we are aware of instances in which DOH staff have advised entities that meet the criteria in section 600.8 not to seek licensure as a DTC, apparently because of the potential impact on Medicaid reimbursement. As we understand it, Medicaid reimbursement to a DTC for the facility fee under APGs, together with reimbursement for the professional services under the Medicaid fee schedule, is usually higher than fee-for-service reimbursement on a global basis to a site organized as a physician office . If it is not in the state's economic interest for a site to become a DTC due to the impact on Medicaid reimbursement, then DOH should consider deleting section 600.8 or modifying it (together with modifying the criteria for establishment and licensure of DTCs) to identify only those entities that DOH believes should be licensed as a DTC and should be reimbursed under APGs for ambulatory services to Medicaid patients. Alternatively, the state should consider modifying its Medicaid reimbursement regulations to provide the appropriate amount of reimbursement for ambulatory patients in each ambulatory setting. We recognize that the state has already made significant revisions in Medicaid reimbursement to ambulatory sites licensed under Article 28 in Part 86-8 of its regulations, and has also approved some increases to physician reimbursement to lessen the Medicaid differential between sites of service. We also understand that, as Medicaid fee-for-service patients transition to mandatory managed care, this difference in reimbursement may disappear, since many managed care companies pay the same amount to DTCs and to physician offices. Nonetheless, as long as Medicaid fee-for-service reimbursement continues to exist, this differential in payment will continue to exist, as well, creating an incentive for DOH staff (i) not to enforce § 600.8 and (ii) to discourage applicants who wish to become licensed as a DTC.

- In the event that physician acquisition or operation of major medical equipment were to be subject to CON review, it would be essential that the need methodologies for this equipment be thoroughly reviewed and substantially updated. To some extent, the need criteria take into account the existing physician resources. However, if physician practices were suddenly to be subject to CON review and if existing physician owned or leased equipment were counted in determining need under the existing need methodologies, the result could well be a determination that there is no need for any additional imaging equipment or linear accelerators —even though an aging population, at greater risk of cancer, may well require substantially more of such equipment. As a result, unless the need methodology is thoroughly revisited, the effect of expanding CON review for the operation of this equipment would be to enact a virtual moratorium on any new capacity, which would stymie both hospitals and physicians from meeting real unmet need.

For the reasons set forth above, we submit that DOH should significantly modify the criteria set forth in section 600.8 or delete this section of the regulations. In conjunction with deciding what criteria to use in a revised regulation, DOH should consider which

entities should be licensed or otherwise regulated under Article 28 of the Public Health Law. DOH should also consider the impact, if any, of Medicaid reimbursement methodologies on the position it takes as to which entities need to be licensed under Article 28 of the Public Health Law. Finally, if DOH expands CON review for any type of facility or equipment to physician practices, it should do so only after reviewing and revising the need methodology.

2. ***Question:*** Should New York State modify its approach to the corporate practice of medicine?

Answer: Yes, for the reasons that follow.

- While there are strong justifications for maintaining a corporate practice prohibition to assure that physicians and other licensed entities control medical service delivery, [3] the existing prohibition on the "corporate practice of medicine" does not take into account the desirability of promoting certain healthcare delivery models. Indeed, this prohibition – if enforced – would hinder use of care delivery models that promote the Triple Aim. This prohibition also creates anomalies in the employment relationships that are allowed and disallowed under NY law, without promoting any legitimate public policy purposes for doing so. Examples follow.

    - Taken to its logical extension, the "corporate practice of medicine" prohibition would bar a hospital from requiring its employed physicians to turn over all fees for professional services rendered at physician office sites that are not on the hospital's operating certificate. This is because the hospital is not "licensed" to operate from these sites, and the prohibition is really a prohibition on the unlicensed practice of medicine by a corporation. [4] The fact pattern noted above implicates not only the prohibition against the "corporate

[3] Thus, we acknowledge that New York State has a legitimate interest in preventing corporations that have no license from any state agency to provide any type of healthcare from employing physicians and holding themselves out to the public as providing medical services.

[4] The prohibition on the "corporate practice of medicine" is – in reality – a prohibition on the unlicensed practice of medicine. That is, it is a prohibition on the employment of physicians by a corporation that has no license issued by the state authorizing it, as part of its licensed duties, to employ physicians to provide healthcare services to the public. Thus, a series of cases interpret this prohibition as providing exceptions allowing corporations to employ physicians as long as the corporation has a license issued by the state that authorizes it to provide healthcare services to the public, such as a hospital or a medical school. See, e.g., *Albany Medical College v. McShane*, 104 AD2d 119, 481 NYS2d 591 (3d Dep't. 1984); aff'd 66 NY2d 982,199 NYS2d 376 (1985).

practice of medicine," but also fee splitting and § 401.2(b) of the DOH regulations relating to operating certificates, which limits where the established operator may operate.[5] See, e.g., *Glassman v. ProHealth Ambulatory Surgery Center,* 23 A.D.3d 522, 806 NYS2d 648 (App. Div. 2d Dept. 2005); rev'd on other grounds in 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010). *See* fn. 7, *infra*. As we note below, in practice these restrictions are frequently disregarded and not enforced.

- In contrast, employed physicians of a medical school can be required to turn over all fees earned at all sites, even sites not on an operating certificate, since a medical school may employ physicians to work at any site pursuant to its faculty practice plan and its charter that allows training of residents. See, e.g., *Albany Medical College v. McShane*, 66 NY 2d 982, 489 NE2d 1278, 499 NYS2d 376 (1985).
- From a public policy perspective, it makes no sense to allow physicians who are employees of a medical school to have an unrestricted practice, but to place restrictions on the physician employees of a hospital.
- The irrationality of this outcome is underscored by the difference in treatment accorded to hospitals whose affiliated medical schools are in the same corporation, compared to those that are in separate corporations.
    - Where a hospital and a medical school are in the same corporate entity, the corporate practice of medicine doctrine, as applied, has allowed the entity to require employed physicians to turn over their income from all sites, even sites not on the hospital's operating certificate.
    - However, where a hospital and a medical school are not in the same corporate entity, the corporate practice of medicine doctrine – together with section 401.2(b) of the Department's regulations - bars the hospital from employing physicians to work at sites not on its operating certificate. It makes no sense for the law to have this anomalous outcome.

- Moreover, under the federal Antikickback and Stark laws, as well as their New York counterparts, the exceptions that apply to physicians who are employees of a hospital give greater flexibility in structuring compensation relationships than the exceptions that apply to physicians who are independent contractors. The state should not, through the "corporate practice of medicine" prohibition, discourage the employment of physicians by hospitals.

[5] Section 401.2(b) provides: "An operating certificate shall be used only by the established operator for the designated site of operation, except that the commissioner may permit the established operator to operate at an alternate or additional site approved by the commissioner on a temporary basis in an emergency."

- For example, many hospitals in New York have established so-called "Captive PCs" in order to structure relationships with physicians who practice at the hospital as well as at non-hospital sites.[6] A Captive PC is a professional service corporation controlled indirectly by a hospital, with the shares in the PC held by a licensed physician who is employed by the hospital with a particular job title, and a shareholder's agreement requiring that physician to relinquish the shares to the next holder of that title if he/she ever ceases to hold such title.
- Under the Captive PC model, the PC employs the physicians. When the physicians are employees of the PC and not of the hospital, the hospital and the physicians do not have the benefit of the more flexible employment exception that exists under the federal Antikickback and Stark laws, as well as their state counterparts. Moreover, complex legal and business issues arise with respect to contractual relationships and the flow of funds between the hospital and the PC.

- In addition, the "corporate practice of medicine" prohibition creates legal issues when trying to structure a network of providers for purposes of contracting with self-insured employers. These networks *arrange* for the provision of medical services, which New York State defines as the practice of medicine. Moreover, an IPA cannot be used to contract with a self-insured employer, since that is not a purpose allowed under Part 98 of the DOH regulations.
- New York State has rarely enforced the "corporate practice of medicine" prohibition, at least in recent years.
  - Instead, this prohibition appears most often to be raised by private litigants in the context of breach of contract lawsuits, where one party seeks to get out of its contractual obligations by claiming that the entire contract should be void as against public policy or that a particular provision should be severed as illegal. See, e.g., *Glassman v. ProHealth Ambulatory Surgery Center, 23 A.D.3d 522, 806 NYS2d 648 (App. Div. 2d Dept. 2005); rev'd* on other grounds 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010).[7]

[6] A physician group practice, whether formed as a PC, a professional limited liability company, or a partnership is permitted, by its license to practice anywhere in the state.

[7] In reversing the appellate court's holding, which had severed as illegal a provision in an employment contract between an ASC and a physician requiring the physician to turn over to the ASC all fees earned at non-ASC sites, the Court of Appeals did not hold that the contested contract provision was legal. Instead, the Court held that the provision was at most "merely malum prohibitum and, therefore, enforceable in a breach of contract action." The court explained that DOH has authority to enforce the provisions of its regulations in section 401.2(b) that authorize an Article 28 facility to operate only from sites on its operating certificate, and that OPMC has authority to enforce fee splitting violations. It also noted that the plaintiff had not "identified an overarching public policy that mandates voiding the contract." 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010).

- Applying this prohibition to hospitals and to networks of providers contracting with self-insured employers, while not enforcing it, creates impediments for law abiding citizens and facilities who are trying to structure legally binding arrangements. This is particularly the case here, since the penalties include criminal penalties. The unlicensed practice of medicine, as well as abetting the unlicensed practice of medicine, are Class E felonies. Ed. L. § 6512.[8]

- As we noted above, in discussing section 600.8, the failure to enforce a law promotes disrespect for the law. If the state is not going to enforce the "corporate practice of medicine" prohibition, it should eliminate it. Of course, this will likely require legislation.[9]

- ***Other Licensed Professionals:*** If the state eliminates or modifies the prohibition on the "corporate practice of medicine," it should also consider eliminating or modifying this prohibition as it applies to other licensed health professions.

- ***Fee Splitting:*** The state should also consider modifying the prohibition against fee splitting to take account of the current and proposed models of health care delivery that are designed to achieve the Triple Aim. The facts that support a charge of violating the "corporate practice of medicine" usually also implicate the prohibition against "fee splitting." Therefore, if you address one prohibition, we suggest that you also consider addressing the other, as well.[10]

Other Observations:

Finally, we share the Department's concern about the lack of access to capital by New York hospitals. We note that this problem would potentially be exacerbated if the Department were to relax the prohibition on the corporate practice of medicine by entities not licensed under Article 28 of the Public Health Law (thereby, in effect, allowing physicians access to capital), while at the same time retaining (rather than relaxing) the

[8] Moreover, willfully violating § 401.2(b) of the DOH regulations is a misdemeanor, with a potential sanction of one (1) year in jail effective 4/1/2014. *See* Public Health Law § 12-b.

[9] However, if DOH were to revise its regulations in section 401.2(b) to authorize a hospital to employ physicians to work at a site not on the hospital's operating certificate so long as the services are not billed as hospital outpatient services (and instead are billed as physician office services), this might obviate the need for legislation.

[10] In this connection, we are pleased that the PHHPC has recommended "relax[ing] the prohibition on revenue sharing among providers that are not established as co-operators" presently prohibited by section 600.9, which is sometimes referred to as "corporate fee-splitting." *See* Recommendation #22 of the PHHPC Report on Redesigning Certificate of Need and Health Planning, adopted 12/6/2012 at p. 46.

CON restrictions applicable to entities licensed under Article 28. We respectfully request that you keep this in mind as you consider potential regulatory and legislative changes.

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March 28, 2013

Ms. Karen Lipson
Director, Division of Policy
Corning Tower, Empire State Plaza
Albany, NY 12237

Dear Ms. Lipson:

A movement is underfoot to drive private medical practice away. Increasingly, physicians are feeling pressured to sell their practices to hospitals where they are promised better insurance reimbursement and relieved of the burdens of managing the business of medicine. Hospitals have joined together which gave them enhanced negotiating power with the insurance companies.

Independent practitioners have only seen their reimbursement rates decline over the past 15 years, while the cost of doing business has continued to increase.

When private practice doctors call the insurance companies directly to try and discuss the need for enhanced reimbursement, we are told that they are not talking to doctors.

Doctors are feeling pressured to keep the cost of medical care down. We are urged to order less testing, order the least expensive test and have had no relief of our malpractice risk.

I have been a practicing obstetrician for almost 30 years and pride myself on being very cost conscious. I have rarely ordered a CAT scan where a sonogram suffices and offer medical management wherever feasible to avoid surgical intervention. Here is the problem that has become clear. If I decide to be acquired by a large hospital, they are in the business of having medical services rendered. The more studies I order, the more the hospital earns from the insurers. The same holds true for surgery, hospitalizations, lab testing, etc.

It seems to me that the insurance companies would be actively talking to private practitioners to try to encourage them to stay independent and reward those who keep costs down. This lack of foresight on their part coupled with the national trend by the hospitals to acquire private practices is going to continue to drive the cost of medical care upward. Instead of rewarding doctors for better outcomes and being cost conscious, the insurance industry is driving private practice away.

Sincere regards,

Denise Lester M.D.

Denise E. Lester, M.D.
DEL/nlp

New York State Academy of Family Physicians

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March 22, 2013

Ms. Karen Lipson, Director
Division of Policy
Office of Health Systems Management

Ms. Joan Cleary Miron, MPH, Director
Division of Primary Care Development
Office of Primary Care

NYS Department of Health
Corning Tower – Empire State Plaza
Albany, NY 12237

Dear Ms. Lipson and Ms. Cleary Miron:

The Academy appreciates the opportunity to comment on recommendations by the NYS Public Health & Health Planning Council regarding extension of the Certificate of Need (CON) process to apply to large medical practices.

We believe that it is appropriate to reassess the purpose and continued need for the CON process given the substantial changes that have occurred in health care since the CON process was conceived. In particular, we feel that the growth in need for health care and the critical shortage of capacity to meet that growing need, compels policy to expedite and accommodate growth and innovation in the network of health care service providers. The CON process is designed to control expansion of health services infrastructure.

In general, the Academy would recommend that the Department develop regulations to measure the impact of ALL providers in a defined geographic market on the overall competitiveness of that market. Your 2/25/13 letter expresses concern regarding the potential for "mega" medical practices to "destabilize safety net providers by attracting commercially-insured patients, while declining to serve Medicaid beneficiaries and the uninsured." The CON process does not account for the effect of hospital growth on community medical practices. It does not protect physicians from business decisions by private plans that jeopardize the economic viability of medical practices. Before the CON process should restrict the ability of large medical practices to form and operate, it should first have a standard for determining how safety net providers might be destabilized by the presence of large medical practices. Furthermore, solo and small group medical practices should be included in the definition of safety net providers. The CON process should include assessment of how solo and small group practices would be affected by the proliferation of mega practices or the expansion of hospital networks.

It is not clear how stability is determined or whether that should be a factor in deciding whether to allow a group of physicians to form a business relationship that may or may not affect local hospitals. Inefficiently operated safety net providers may be threatened by any competition just because they themselves are poorly managed.

The letter also expresses concern with "excess utilization due to self-referral." There is no process delineated to compare the cost or quality of the services that are most likely to be provided by mega practices (i.e., certain surgeries, radiation therapy and imaging) as opposed to the local hospital providing the same services. If the same services provided by a mega practice are cheaper or more effective, then the fact that physicians in the practice who provide those services are ostensibly self-referring should be irrelevant. If self-referrals are occurring when there is no medical necessity then that should be addressed through legal or professional misconduct procedures. It should not be a factor of the CON process. Furthermore, if self-referral is inherently bad then it should not be permitted by hospital networks which acquire or establish primary care capacity and then require primary care providers in the network to refer patients to hospital provided services.

The Academy does not see value in subjecting medical practices to the CON process unless and until that process is reformed to allow the impact of growth in provider capacity to be objectively determined and assessed. The CON process should not be used to protect hospitals from competition by medical practices that operate beyond the control of the hospital.

Thank you for your invitation to comment on the Council's recommendations. We look forward to working with you to further address the CON process and the recommendations of the Council.

Sincerely,

Philip Kaplan, MD
President

THE NEW YORK STATE RADIOLOGICAL SOCIETY, INC.
A CHAPTER OF THE AMERICAN COLLEGE OF RADIOLOGY
www.nysrs.org

March 25, 2013

Ms. Karen Lipson
Director
Division of Policy
Office of Health Systems Management
New York State Department of Health
Corning Tower
Empire State Plaza
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Ms. Joan Cleary Miron
Director
Division of Primary Care Development
Office of Primary Care
New York State Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

Re: DOH Letter of February 25, 2013

Dear Ms. Lipson and Ms. Miron:

I am writing on behalf of the New York State Radiological Society ("NYSRS") in response to your letter of February 25, 2013, soliciting responses to several questions relating to scope of the certificate of need ("CON") and licensing laws. Thank you for the opportunity to comment.

The NYSRS appreciates the importance of the questions you have posed. The structure of hospitals, the size of medical practices, the employment status of physicians, and the business arrangements between hospitals and physicians are changing rapidly. Radiologists, in particular, are much more likely to be hospital or mega-practice employees now than they were just five years ago. It is important that statutes and regulations governing these relationships are continually reassessed to assure that they achieve their desired effect.

The NYSRS sees "mega-practices" as an inhomogeneous but rapidly evolving and expanding form of health care delivery. Our impression is that each mega-practice, however defined, is distinct. Some have acted in a predatory manner and have had a negative effect on healthcare delivery in New York State, driving up healthcare costs through self-referral. Others are more benign and have actually promoted quality and access. In this regard, the NYSRS strongly supports the application and enforcement of current antitrust, physician discipline and self-referral laws on these and all physician practices. In addition, we expect that mega-practices

that seek to qualify as accountable care organizations ("ACO's") will be required to adhere to the quality and operational standards applicable to ACO's.

The NYSRS believes that medical decision-making should remain the exclusive province of licensed physicians, and not business managers. We want mega-practices and other new service delivery vehicles to be actively controlled by physicians who are not mere figureheads for corporate investors and managers. To assure this, we encourage the Departments of Health and Education and other state agencies to enforce the corporate practice prohibition now in statute.

The NYSRS does not support the extension of CON requirements to radiation therapy or advanced imaging equipment. We believe that market forces will correct any over investment in equipment.

Finally, we share the concerns of the Medical Society of the State of New York about retail clinics. We do not believe these facilities increase access or reduce costs. They merely channel patients to other providers, drive up demand and increase health care expenditures. We see no justification for statutory or regulatory changes to facilitate their growth.

Thank you for your consideration of the NYSRS views.

Sincerely,

Bonnie Litvack, MD

Bonnie Litvack, M.D, FACR
President, NYSRS

Greater New York Hospital Association
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Kenneth E. Raske, President

GNYHA Response on Physician Practice Oversight
April 2013

The New York State Department of Health (DOH) is assessing whether and how to increase regulation of large physician practices. In a February 25, 2013, letter to stakeholders, DOH sought extensive input on "the risks and benefits presented by the growth of enhanced physician practices and the appropriate level of state oversight of their activities" and particularly questioned the impact of specific lines of service such as office-based surgery, advanced diagnostic imaging, and radiation therapy on community providers and public health.

DOH's inquiry follows a December 2012 recommendation from the Public Health and Health Planning Council (PHHPC) to review these issues. In its recommendation, PHHPC asked for consideration of the cost, quality, and local impact of identified services such as surgery, imaging, and radiation therapy when performed in physician practices and facility settings.

To respond to DOH, GNYHA convened a high-level executive workgroup representing a range of member hospitals, including Chief Executive Officers (CEOs) and other senior leaders. This group met three times between February and April 2013 and reached the conclusions outlined below, which were subsequently presented to and approved by the GNYHA Board of Governors.

GNYHA Conclusions

1. **GNYHA members do not believe that regulation of physician practices in any form is a solution to the larger systemic problems confronting providers in Brooklyn and other troubled areas throughout the State. Increased regulation is not the right way to stabilize our safety net.**

   As noted, DOH's February 25 letter to stakeholders seeks extensive input on the impact of evolving physician practices and the State's role in overseeing them. DOH also poses

questions on wide-ranging aspects of corporate practice of medicine and applicable State regulations, among other issues. The broad inquiry suggests that DOH is contemplating oversight tools to manage changing health care delivery in our State, particularly in areas like Brooklyn where the staggering difficulties of inadequate reimbursements, patient complexity, and other factors contribute to a legitimately confounding climate. This enormous challenge is, we fear, too vast to be addressed through regulatory intervention. We do not believe that the imposition of Certificate of Need (CON) requirements and related oversight should be used as a solution to the difficulties facing community hospitals and safety net providers in Brooklyn and elsewhere in the State.

Instead, we support a disciplined approach to these larger issues through appropriate channels, including the Medicaid Redesign Team (MRT) Waiver request to the Centers for Medicare & Medicaid Services. The nearly $3 billion in funds anticipated through the Waiver for safety net hospitals, including the Vital Access Provider (VAP) program and Capital Stabilization program, are critically needed to transform and restructure the health care delivery system in Brooklyn and other areas of the State to ensure continued access to care for communities, and to achieve the goals of the MRT and the Triple Aim. GNYHA is committed to continuing our work with the State to advance this and other solutions in a targeted way.

2. **GNYHA members oppose comprehensive regulation of physician practice groups as facilities under the State's CON process, licensure authority, or otherwise.** At this point, GNYHA members do not want physician practices treated as Article 28 providers. Such regulation would be unnecessarily burdensome, particularly as we move towards more integrated models of care delivery, and neither the State nor our members have sufficient resources for massive regulation of a new class of providers.

   There is no doubt that physician groups are an increasingly significant component of health care delivery across New York. As State and national policy direct us towards an integrated model of health care, GNYHA members are placing additional significance on coordinating physician practice and hospital services. At the same time, large corporate "mega practices" are growing rapidly. In all of this transition, some hospitals are concerned that evolving

physician groups are imperiling access to care by steering away patients and undermining hospital financial stability.

Nonetheless, even hospitals most likely to be impacted by large physician practices have indicated that across-the-board financial or regulatory restrictions on these groups are not useful steps to take at this point. GNYHA members are presently reluctant to over-regulate the practice of medicine, create additional administrative burdens for providers and the State, and curtail marketplace flexibility and creativity.

3. **GNYHA members encourage DOH to collect robust data to assess the quantity and impact of evolving physician practices**. **Without adequate information, we cannot understand the scope of the problem.** While we may observe a growth of physician practices anecdotally, it would be helpful to have a clearly defined sense of the quantitative extent of the phenomena and its impact on existing providers and patients before engaging in any regulatory activity. As stakeholders, we are all uncertain of the quantity, scope, and characteristics of such practices and their impact on existing providers and access to care. We therefore respectfully suggest that DOH initiate a disciplined review of existing market conditions to ease confusion and serve as a guide for any future action.

   Such an analysis might include data points such as:

   - Practice location
   - Services provided
   - Current use/ ownership of relevant equipment
   - Payer mix
   - Volume by payer
   - Patient origins
   - Hospital affiliation
   - Impact on local hospitals
   - Any quality of care metrics

This assessment would then be coupled with the qualitative information DOH receives in response to its February 25 request letter, providing a more informative picture of the market and scope of any specific problem to be addressed. Such data would be a useful starting point for any short-term oversight and help create a reference point for study of the health care delivery system.

4. **GNYHA members support only targeted oversight of specific equipment and service lines—including advanced diagnostic imaging, radiation therapy, and surgery—regardless of setting.** To the extent that hospitals and other facilities already face CON requirements and related oversight in specific clinical areas, so too should all providers. GNYHA believes such regulation can not only level the playing field for facilities but better support the Triple Aim by decreasing over-acquisition and unnecessary utilization, driving efficiency, and promoting public health.

   As PHHPC and DOH have noted, some specific equipment and service lines are currently regulated when offered in a hospital or facility yet unregulated in a physician practice. The State has specifically pointed to office-based surgery, diagnostic imaging (CT scans, MRIs, and PET scans), and radiation therapy as such service lines, suggesting that insufficient oversight of these specific items could drive overutilization and negatively impact neighboring hospitals and public health. Our members have confirmed that when physician practices offer such ancillary services, they divert patients, particularly the commercially insured, from the hospital setting. They also drive unnecessarily utilization. Moreover, our members have identified quality problems with the use of high-end technology by some physician practices in their communities. Yet, broadly speaking, physician practices need not go through CON or any licensure process to acquire and use the relevant equipment or provide the actual care. GNYHA members have raised similar concerns about currently unregulated stand-alone urgent care centers.

   Thus, our members support leveling the playing field in a straightforward way: if hospitals or clinics are required to seek approval and undergo monitoring when offering identified services, those services should be regulated regardless of the provider setting. This regulatory parity will help stabilize essential hospitals and address cost and public health concerns

stemming from excessive acquisition and utilization of high-end imaging and radiation equipment in particular.

Some GNYHA members have discussed initiating State regulation for the service lines already highlighted: imaging equipment such as MRIs, PET scanners, and CT scanners; equipment and provision of therapeutic radiology; and surgical procedures. Note, however, that this is not a unanimous or definitive list. Other GNYHA members have concluded that MRIs and CT scanners are now so common as to not require any regulation or have suggested that equipment that has been on the market for a significant amount of time no longer needs to be regulated at all. GNYHA members have indicated that they will provide specific feedback about any additional or more targeted service lines that should be regulated, and we will work with DOH and PHHPC to determine if expanded or decreased oversight is required.

Significantly, any check on acquisition and use should be done based on a thoughtful need methodology and reliable data. Respectfully, DOH and PHHPC have struggled at times with appropriate need methodology and inadequate data as they review licensure applications. "Need" can only function as a meaningful metric if it is established and measured reliably, and we encourage the State to work with partners in government and the provider community on necessary improvements. GNYHA is ready and willing to work with the State on this process.

5. **GNYHA members have differing opinions regarding social benefit requirements as part of any new CON process for designated equipment and services.** Should the State decide to regulate specific equipment and services in currently unregulated physician practices, some GNYHA members want to include social benefit requirements—service to Medicaid and uninsured patients, coordination with community providers, and others—as part of the CON review process.

   Drilling down further, some GNYHA members believe that if a social benefit requirement were to be imposed on a hospital-affiliated physician practice that is currently unregulated,

the hospitals' socially beneficial activities should be counted towards satisfying that physician practices' social debt. In other words, the socially beneficial contributions of the entire hospital or hospital system should be considered in assessing the physician group's CON application. In contrast, some GNYHA members feel that any social benefit requirement imposed must be met only by the specific physician group or practice location applying to acquire or provide the relevant equipment or services. There is simply no consensus.

The State seems to share this ambivalence. In its December 2012 report, PHHPC acknowledged that CON can function as "an all-purpose lever to condition market entry or expansion on actions that support policy goals (such as Medicaid access or charity care)." But at the same time, PHPPC noted that CON can be too much of a "blunt instrument" and needs to be readjusted to, among other things, better address the impact of physician practices on essential providers and their communities. In any event, GNYHA continues to emphasize that CON is a powerful tool that should be used only sparingly towards clear and beneficial objectives. The overall role and value of the CON process is a larger issue for debate, and GNYHA will continue to contribute to this important discussion.

Moreover, our members all agree that even if social benefit requirements are imposed on currently unregulated providers seeking to acquire or offer the high-end equipment or services in question, no new requirements should be added to the existing hospital review process.

GNYHA Concerns

There are, of course, potential shortcomings in supporting additional regulation and oversight.

- **DOH has limited resources.** Whatever path DOH and PHHPC choose, they will confront the reality of limited personnel and resources. Though GNYHA members have worked to shape their recommendations within existing CON infrastructure, in part to require the expenditure of as few new resources as possible, the State is quite constrained. These proposals will require a great expenditure of State resources, and there is some fear that any

additional oversight and regulation will slow down an already clogged system and add delays and costs for all involved.

- **Increased oversight should apply to existing practices.** Our members have noted that physician practices that already possess and provide the specific pieces of equipment and services should not be left unchecked. These practices currently impact hospitals and other providers in their communities and should be taken into account. This might be done initially through a registration process, which would at least provide the State with more data, and eventually through more heightened regulation imposed as practices seek to replace or upgrade their equipment or services. Regardless of how it is managed operationally, our members suggest that any new regulations apply to existing and new providers equally.

- **Any new regulations must truly be applied across the board.** Increasingly, payers are creating or working with physician practices that offer the imaging, radiation, and surgical equipment and services we are discussing. Should new regulations be imposed on these specified service lines, they must apply when they are acquired or offered by physician groups affiliated with insurance companies as well. Payer-affiliated groups must go through the same CON process as independent or hospital-affiliated physician groups. Further, our members recommend that if a payer cannot demonstrate need for the equipment or service, it must work with existing providers in the community to offer it. Without this check, GNYHA members are concerned that the playing field will again tilt against them.

- **Increased regulations could add to hospitals' administrative burden.** Though many hospitals provide the equipment and services at issue through facilities or ventures already subject to State approval, unregulated hospital-affiliated physician practices may also offer these service lines. If DOH regulates regardless of setting, this could include those hospital-affiliated physician practices. Just as DOH has limited resources, so too do many hospitals, and there are concerns that any additional regulation could add to hospitals' burden.

- **Additional regulation is not a comprehensive solution for the hospitals impacted by growing physician practices.** GNYHA members thus far agree that across-the-board

regulation of physician practices is not a productive solution to the complex problems facing our community hospitals and safety net providers. However, we acknowledge that the more tailored approach we recommend here is likewise not the answer to these concerns, but a smaller solution to a smaller problem. We therefore respectfully request that the State continue its work on the larger concerns facing our hospitals and health care system in Brooklyn and elsewhere, regardless of any new steps it takes to oversee physician practices. The steps we propose here are indeed meaningful, but also necessarily limited.

Conclusion

GNYHA and its members are pleased to work with DOH and PHHPC as they consider these suggestions and this issue broadly. Though New York's health care delivery system continues to evolve, its hospitals serve a specific and essential role in care delivery and community building. Hospitals should be acknowledged and supported appropriately, and targeted oversight of identified equipment and services, regardless of setting, is one positive step towards that goal.

HANYS Healthcare Association of New York State

Proud to Serve New York State's Not-For-Profit Hospitals, Health Systems, and Continuing Care Providers

Daniel Sisto, President

May 7, 2013

Nirav Shah, M.D., M.P.H.
Commissioner of Health
New York State Department of Health
Empire State Plaza, Corning Tower Building, 14 Floor
Albany, NY 12237-0001

Dear Commissioner Shah:

I write in response to the Department of Health's (DOH) February 25 letter regarding oversight of "enhanced physician practices" and as a follow up to our April 10 meeting with DOH on this issue. HANYS appreciates the opportunity to participate in this important dialogue and provide input on behalf of our hospital and health system members statewide.

During numerous sessions of the more than year-long deliberations by the Public Health and Health Planning Council (PHHPC) regarding Certificate of Need (CON) reform, HANYS and several PHHPC members have consistently stressed the need for "leveling the playing field" between Article 28-licensed providers subject to CON and other DOH rules, and private practitioners not subject to those rules, with regard to the provision of the same type of services.

HANYS has held numerous discussions on this issue with member hospitals across the state, internal member work groups, and our board of trustees. Our members are in strong agreement on the following issues:

- First and foremost, our members are very concerned about the advantage the state provides to for-profit providers of care that do not generally serve Medicaid and uninsured patients. Those providers are not bound by CON restrictions and delays, rigorous facility structural requirements and associated expenses, or DOH operational requirements that reduce flexibility and add cost, even though they provide many of the very same services as licensed facility providers. This advantage must cease.

- HANYS' members are very concerned about DOH's current human resource capabilities. The limited and seemingly ever-shrinking staff assigned to carrying out current CON and other oversight responsibilities already create undue delays. Any additional workload responsibilities DOH decides to assume would necessarily require more personnel resources to accomplish. Without additional resources, delays currently being experienced will worsen and will impede the health care field's ability to reconfigure, as desired by the state.

- Only addressing enhanced physician practices as defined by DOH will not create a level playing field. To truly level the playing field, the same rules must be applied to all providers of the same type service, including small private practices and services such as urgent care that function outside the regulatory environment.

While our members agree on key issues that must be rectified, there is less consensus with respect to solutions. We will continue this discourse with our members and appreciate the opportunity to represent their views before DOH and PHHPC.

In our discussions with DOH, it was clear that we all recognize that there are a range of complexities associated with these issues. HANYS looks forward to a continued productive dialogue with DOH and PHHPC to identify appropriate responses that we hope will result in the highest quality care possible for all New Yorkers.

Sincerely,

Dan Sisto

Daniel Sisto
President

DS:sm

cc: Karen Westervelt
PHHPC Planning Committee