Just Roll With It

Using a mobile femtosecond laser for cataract surgery is a sensible — and instantly profitable — way to bring the latest technology to your ASC.

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Proven therapeutic utility in blepharitis, conjunctivitis, and other superficial ocular infections

- Profound bactericidal effect against gram-positive pathogens
- Excellent, continued resistance profile—maintains susceptibility, even against methicillin-resistant Staphylococcus aureus
- Ointment provides long-lasting ocular surface contact time and greater bioavailability
- Anti-infective efficacy in a lubricating base
- Unsurpassed safety profile—low incidence of adverse events
- Convenient dosing—1 to 3 times daily
- Tier 1 pharmacy benefit status—on most insurance plans

Bacitracin Ophthalmic Ointment is indicated for the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

Important Safety Information

The low incidence of allergenicity exhibited by Bacitracin means that adverse events are practically non-existent. If such reactions do occur, therapy should be discontinued.

Bacitracin Ophthalmic Ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic.

This product should not be used in patients with a history of hypersensitivity to Bacitracin.

Please see adjacent page for full prescribing information.

Bacitracin Ophthalmic Ointment USP
STERILE Rx Only

DESCRIPTION: Each gram of ointment contains 500 units of Bacitracin in a low melting special base containing White Petrolatum and Mineral Oil.

CLINICAL PHARMACOLOGY: The antibiotic, Bacitracin, exerts a profound action against many gram-positive pathogens, including the common Streptococci and Staphylococci. It is also destructive for certain gram-negative organisms. It is ineffective against fungi.

INDICATIONS AND USAGE: For the treatment of superficial ocular infections involving the conjunctiva and/or cornea caused by Bacitracin susceptible organisms.

CONTRAINDICATIONS: This product should not be used in patients with a history of hypersensitivity to Bacitracin.

PRECAUTIONS: Bacitracin ophthalmic ointment should not be used in deep-seated ocular infections or in those that are likely to become systemic. The prolonged use of antibiotic containing preparations may result in overgrowth of nonsusceptible organisms particularly fungi. If new infections develop during treatment appropriate antibiotic or chemotherapy should be instituted.

ADVERSE REACTIONS: Bacitracin has such a low incidence of allergenicity that for all practical purposes side reactions are practically non-existent. However, if such reaction should occur, therapy should be discontinued.

To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-886-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION: The ointment should be applied directly into the conjunctival sac 1 to 3 times daily. In blepharitis all scales and crusts should be carefully removed and the ointment then spread uniformly over the lid margins. Patients should be instructed to take appropriate measures to avoid gross contamination of the ointment when applying the ointment directly to the infected eye.

HOW SUPPLIED:
NDC 0574-4022-13 3 - 1 g sterile tamper evident tubes with ophthalmic tip.
NDC 0574-4022-35 3.5 g (1/8 oz.) sterile tamper evident tubes with ophthalmic tip.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].
I am very pleased to introduce the first issue of The Ophthalmic ASC published in partnership by Ophthalmology Management and the Outpatient Ophthalmic Surgery Society.

You’ve known The Ophthalmic ASC as a quarterly supplement to Ophthalmology Management. We’re transforming this publication into a more comprehensive journal with substantive and up-to-the-minute information and insights on topics that relate to management, operations, surgical procedures, and regulations — essentially anything and everything that affects the ophthalmic ASC.

The Ophthalmic ASC is now an official publication of OOSS University. Our association with OOSS provides prodigious resources. The Ophthalmic ASC will also be available to OOSS members on the organization’s website.

At left, you’ll see the names of our first editorial board — prominent physicians, administrators, nurses and other professionals who’ve been chosen to represent a cross section of ASC disciplines. Their knowledge, experience and expertise will enhance and inform journal content.

It’s an extraordinary experience to unveil a new and innovative journal dedicated exclusively to the ophthalmic ASC community — and a milestone. We’ve come a long way since those early days when the pioneers of our industry were seen as quixotic and sure to fail. Don Quixote, that idealistic Man of La Mancha, who attacked windmills in the name of chivalric romance, proved the wise and noble ideal that individuals can be right even when society is quite wrong. And so it was with the early advocates of ophthalmic ambulatory surgery.

There are those today who say that to fight restrictive government policies and regulations is to tilt at windmills. I don’t see it that way. We can inform the debate, advocate and educate. We can provide credible and persuasive evidence that one size does not fit all when it comes to patient care in the ophthalmic ASC. We can work with government regulators to forge solutions — for the benefit of our patients and our industry. We can — and do — win. The growth of our noble model for delivering high quality, affordable surgical care is the best evidence of our success.

I like to believe that ophthalmologists are a noble group. Sure, just like Don Quixote, we can be a bit crazy, but with ventures like this journal, we continue to inspire.

William J. Fishkind, MD, FACS, is Chief Medical Editor of The Ophthalmic ASC and past President of OOSS. He is Director of the Fishkind, Bakewell & Maltzman Eye Care and Surgery Center in Tucson, Ariz.
AL-Scan has made my practice more efficient and given us additional capabilities. We no longer send out—we do everything in-house. AL-Scan's compact design was perfect for our offices here in Manhattan. Nidek's reputation as one of the best manufacturers was a big factor in our decision.

— Jeffrey D. Nightingale, MD, FACS

THE AL-SCAN OPTICAL BIOMETER incorporates NIDEK's much acclaimed 3-D auto tracking and auto shot, which provides the operator with speed, ease of use, patient comfort, and accuracy.

- Measures 6 Values in 10 seconds: AL, ACD, CCT, K, PS and WTW
- 3-D auto tracking and auto shot for enhanced ease of use
- Enhanced possibility to measure cataractous eyes
- Optional built-in ultrasound biometer and pachymeter
- Anterior segment observation with imaging of lens, pupil, and double mire rings
- IOL calculation with its own measured values
- Toric assist function
- Scheimpflug image

Visit our website to download our brochures.
On-demand mobile surgical solutions for femtosecond laser-assisted cataract surgery are allowing ASCs to plow through past barriers to make this state-of-the-art technology available to surgeons and their patients. All types of surgery centers are taking advantage of the mobile and/or rental option. These ASCs can be found in both rural and metropolitan areas and may be ophthalmic-focused or multispecialty centers. While most facilities initially take the mobile approach to phaco surgery because their beginning case volume is too low to justify purchasing a laser, some have passed the break-even point but prefer to stick with the mobile option, appreciating its advantages:

- the technology is available at the ASC without the large capital expenditure and high annual maintenance fees associated with purchasing a laser
- revenue is generated with each use; there’s no wait to arrive at a cost-income break-even point
- the laser is always up-to-date; no worries about upgrading or obsolescence
- no need to hire additional staff to handle laser operation and maintenance
- the laser only occupies space in the facility when it’s being used
- the ASC can use the availability of the laser to attract new surgeons who want to use a femto laser.

Using a mobile femtosecond laser for cataract surgery is a sensible—and instantly profitable—way to bring the latest technology to your ASC.

By Desiree’ Ifft, Contributing Editor
Two providers of mobile surgical equipment that have added femtosecond lasers for cataract surgery to their service offerings are Sightpath Medical (sightpathmedical.com) (Figure 1) and ForTec Medical (fortecmedical.com) (Figure 2). In business for 26 years, ForTec’s first mobile equipment offering was a YAG laser for ophthalmology. Today, the company provides mobile technology to more than 10 medical specialties, averaging 60,000 equipment mobilizations per year. Sightpath, which focuses on ophthalmology, recently logged its 2 millionth procedure.

Kelly Clayton first became familiar with the benefits of utilizing mobile laser technology in the context of LASIK more than 10 years ago. Today, he sees the same success with mobile femtosecond laser technology for cataract surgery at Richens Eye Center in St. George, Utah, where he’s the practice administrator. Sharon Richens, MD, who co-owns the Coral Desert Surgical Center, also in St. George, uses a LenSx laser (Alcon) supplied by Sightpath. “The mobile option was really the only option for us when we considered the total overhead of a femto purchase,” Clayton says. “It gave us the ability to introduce the new technology to our patient population without the need for a patient volume that we felt was unattainable right out of the gate. The mobile platform was profitable on day 1 and had we purchased a laser, that would not have been the case. We’ve always been able to meet the minimum number of cases specified in our Sightpath contract. In fact, we quickly exceeded the minimum and began requesting more days with the laser. Patient acceptance has continued to increase because of great surgical results and effective marketing.”

Jeffrey Starkey, MD, who practices with the NEOVision Group in Akron, Ohio, and is one of several owners of the Parkwest Surgery Center, is convinced that femtosecond laser technology has taken a good procedure and made it better, improving his outcomes. “By contracting with ForTec to bring the Catalys laser (Abbott Medical Optics) to the ASC only when I want to use it, I get to use a technology I’m very excited about not carrying the risk of buying or leasing it,” he says. “I don’t have to think about the possibility that I may not like a particular laser platform or that it may become obsolete before I’ve earned return on my investment. At the end of the day, I don’t have to pay for an annual maintenance agreement or keep the laser running and calibrated. ForTec takes care of that.”

**How the Mobile Option Works**

Drs. Starkey and Richens are the only surgeons at their ASCs using the femtosecond cataract laser technology for cataract surgery. For December 2014, Jeffrey Starkey, MD, had scheduled ForTec Medical to bring the Catalys femtosecond laser (Abbott Medical Optics) to the Parkwest Surgery Center in Akron, Ohio, on 4 days. He operated on 10 to 14 eyes during each visit. The laser arrives the night before surgery, and the ForTec technician sets it up in a procedure room where the ASC houses a YAG and other lasers. “When we built the center, we had a verbal agreement with a group of pain management doctors that didn’t work out, so we now have this large extra room, right outside the OR door, which works well for our femtosecond laser days,” Dr. Starkey says. “The Catalys has its own fixed bed, so some facilities keep it in an OR, but we move our patients around in a wheelchair.”

The technician calibrates the laser and is present for the entire procedure, helping Dr. Starkey to navigate the screens efficiently. One of the ASC’s RNs is in the OR as well. Dr. Starkey’s surgical coordinator is also at the surgery center on femtosecond laser days. “It’s not absolutely necessary for her to be there, but we like her to be because she’s a familiar face to patients. She talks with them, supports them and keeps them comfortable.” Dr. Starkey usually starts the femtosecond surgery part of the day by consecutively marking three eyes in the prep area. While the first patient is getting prepped and draped, he performs the Catalys part of the procedure on two consecutive patients in the procedure room. After finishing the first case in the OR, he speaks briefly with that patient’s family, marks another eye, uses the Catalys on the next patient and then goes back into the OR. “So it’s mark, femto, phaco,” he says.

**Some tips from Dr. Starkey:**

- Designate someone in the ASC who can function like a field general, helping the surgeon to figure out the most efficient process for the laser and directing him where to go next.
- Surgeons and ASCs should plan on the femto cases taking twice as long at first as they will after more experience. Schedule enough time to avoid stress about falling behind schedule.
tosecond laser for cataract surgery, so they have contracts with the mobile technology companies (as opposed to some situations in which the facility is contracted with the mobile tech company). ForTec offers 1-year contracts, while Sightpath contracts last 3 years. Each company charges per procedure for use of the mobile laser and sets a minimum number of eyes per visit.

ForTec requires a minimum of eight procedures per visit and 60 procedures annually for the ASC. Surgeons operate on 10 eyes to achieve certification for using the laser. Once the surgeon is certified, the eight-eye minimum isn’t enforced for the subsequent two laser visits. Also, the company doesn’t require the contract to be signed until after surgeon certification. “We try to make it risk-free and as economical as possible for the customer to get in,” says Patrick Filipovitz, ForTec Medical’s VP of Sales and Marketing. Sightpath’s only requirement is that a minimum of six eyes per laser visit be performed. With both companies, the per-procedure price decreases with volume, i.e., the number of cases performed during a visit.

According to Tim Warrell, Marketing Manager at ForTec Medical, how ASCs schedule their laser visits varies. For example, one center has six to eight surgeons using the laser, and they cluster all of their surgeries into 1 week per month. “That’s smart for pricing,” Warrell says. “That type of scheduling, having the laser for several days in a row, can push the cost to below $700 per procedure. It’s higher when the laser is stopping at a location for 1 day a week.” Volume drives down the price for surgeons and ASCs using Sightpath’s services as well. “Our customers average about 10 eyes per stop,” says Joel Gaslin, Vice President of Sales and Marketing at Sightpath. “Some of them, however, have the laser for multiple days at a time. We’re at one ASC, for example, for 3 days every other week. In those latter scenarios, the cost per procedure goes below $700.”

The per-procedure fee includes the services of a technician who travels with the femtosecond laser and is trained by the manufacturer to set up,
calibrate, ensure proper operation and, if necessary, repair the laser. ForTec says its technicians also can assist during the procedure by programming the laser settings at the surgeon’s request or helping to manage the flow of patients to and from the laser. Sightpath notes its technicians can assist with the procedures and also specialize in keeping patients calm and comfortable before, during and after the procedure. “The technician is something our customers really appreciate,” says Sightpath’s Gaslin.

Value-added Services for Planning and Marketing

Representatives from Sightpath and ForTec understand that the incorporation of femtosecond laser-assisted cataract surgery ASC involves far more than the equipment, so they offer help in making the transition. “We assist with steps in the adoption process so they can get up and running quickly and effectively,” ForTec’s Warrell says. “We provide marketing assistance, such as promotional materials, information and graphics for websites, and tablets with educational animations for patients, and we encourage pre-launch planning meetings for clarification of key issues, such as staff roles.” The company is also hosting 32 educational workshops across the country in which surgeons can learn from opinion leaders and colleagues who have experience with femto.

“We help our customers think in global terms of adding a procedure,” Sightpath’s Gaslin says. “We’re building an inside agency comprising writers, designers, marketing professionals and people who are knowledgeable about market trends. We have a 75-day plan that builds case volume while preparing practices for their femtosecond launch. We cover the ‘four Ps of marketing’ (product, price, place and promotion) by providing practice development tools,

CONTINUED ON PAGE 17

Femtosecond Cataract Surgery Days at Coral Desert Surgical Center

In December 2014, Sightpath Medical delivered the LenSx femtosecond laser to the Coral Desert Surgical Center on two separate days. On each of those days, Sharon Richens, MD, operated on about 12 eyes. This year, the laser is scheduled to be at the center 3 days per month. “We coordinate our femto days closely with the ASC and give them our scheduled days a year in advance,” says practice administrator Kelly Clayton. At each visit, the Sightpath technician sets up and calibrates the laser in one of two rooms. One option is a pre-op room that’s used less often than others, mainly for pediatric patients. The other option is an endoscopy room, which is large and only used once per week. “We prefer not to occupy one of the ORs with the laser because working out of just one OR decreases efficiency and profitability for both the surgeon and the ASC.”

He continues, “We’ve found that starting with a traditional cataract surgery as the first case of the day is very helpful. The flow is as follows: While the ASC is prepping the traditional case in the OR, the surgeon is performing the first femto case. The surgeon then performs the traditional procedure in the OR while the first femto case is being moved to the second OR and the second femto case is being moved into position in the laser room. When the surgeon finishes the first case in the OR, she goes back to the laser room for the next femto case and then to the second OR where the first femto case is now ready. She continues to go from OR to laser room until all cases are completed.”

Some tips from Clayton:

- A key factor for success with femtosecond laser-assisted cataract surgery is staff buy-in, including the practice’s optometrists. “We had every member of the staff, over a month period of time, watch Dr. Richens perform femto surgery so they could see the amazing technology in action,” he says. “This got them excited about the procedure but also gave them the ability to talk about it with the patients and their families. Having every staff member out of the office for a half day watching surgery was costly but it was a great way to help them — and in turn patients — see the benefits of this new technology.”

- Clayton also notes, “To really make this project successful and profitable, the practice should have a surgical counselor who can explain the surgical options, including premium IOLs, in detail to each patient. For us, this occurs after the surgeon has seen the patient and made a surgical recommendation. If you have the right counselor, he or she is well worth the expenditure. We have two surgical counselors who are ultimately responsible for helping patients decide on their surgical options based on the surgeon’s recommendation.”

- Marketing can be expensive, but it builds volume. “It has been a huge help in introducing femtosecond technology to our area,” Clayton says. “We were the first to offer it, and we capitalized on this fact. We’ve used print, radio, patient seminars, health fairs, e-mail to our existing patient base, billboards and ads on the side of city buses.”

CONTINUED ON PAGE 17
n old administration, a new Republican Congress and, yes, more partisanship and legislative gridlock — what does this mean for our health care system? Will healthcare reform be repealed, derailed or substantially modified in the upcoming year? Will patients, angry at the prospect of losing their existing coverage and physician networks, avoid the new insurance mandate and opt to give up coverage altogether? Will sustainable growth rate (SGR) be resolved in 2015 or 2016 — or even in our lifetimes? For purposes of forecasting how our ASCs will be paid and regulated, does the resolution of these “big picture” political, health policy, economic and regulatory matters really make a crucial difference?

In this series of two articles, I’ll focus on the activities coming out of the Nation’s Capital that have the potential to impact the delivery of care by ophthalmic ASCs. What will ASCs be paid? What will hospitals be paid? How will ASC quality and outcomes be measured? How will our centers be regulated? And, importantly, what can the ASC surgeon and staff do to strengthen the voice of the ASC and our ophthalmology communities in Washington?

**ASC Payments in 2014**

In late November, CMS published its final 2015 ASC payment regulation. The agency is updating rates by 1.4%. With respect to eye surgery, the following is a representative sampling of high-volume procedures and their payment rates.

The ASC industry is dissatisfied with the annual updates provided to our facilities and will continue to strenuously object to CMS’s use of the Consumer Price Index-Urban (CPI-U) as an inflator, urging instead that facilities should be afforded the Hospital Market Basket, which is provided to hospital outpatient departments and is typically about a point higher. Because ASCs treat the same patients for the same conditions and consume comparable resources in delivering surgical care, there is no justification for ASCs receiving a lesser increase than hospitals. We’ll continue to raise concerns regarding the impact of these irrational and arbitrary cost-

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**Final 2015 ASC Payment Rates for Ophthalmic Services**

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of-living differentials on the growing disparity in payment rates between ASCs and hospitals.

Finally, as a failsafe, the ASC community will introduce and seek passage of legislation this year for The ASC Quality and Access Act of 2015, which, among other items, would direct CMS to provide ASCs with the same annual update as hospitals. This bill would accomplish a number of additional objectives: add an ASC voice to the Advisory Panel on Hospital Outpatient Payment (important since our rates are based on hospital payments) and require CMS to disclose the criteria it uses to determine which procedures may be performed in the ASC setting.

**Cost Reporting for ASCs**

For years, the Medicare Payment Advisory Commission (MedPAC) has recommended that Congress require ASCs to submit to some form of cost reporting as a condition for receiving an annual update. The ASC industry will continue to oppose any form of facility cost reporting. Why? The rates ASCs are paid are based on payments to hospital outpatient departments (HOPDs). As such, ASC costs are irrelevant. Moreover, the administrative and financial burden on surgery centers would be substantial. We’re pleased that the 2015 payment rule doesn’t include a cost-reporting mandate, nor do we believe that Congress — at least at this juncture — will adopt one.

**Leveling the Playing Field Between ASCs and Hospitals**

Federal policymakers are at last beginning to understand the perverse consequences emanating from a reimbursement system that overpays hospitals and underpays ASCs for providing the same services. For the first time in the 30-plus year history of the ASC industry, about as many surgery centers are closing as are opening each year. Moreover, hundreds of millions of Medicare dollars are being wasted as hospitals acquire ASCs and convert them to HOPD status to secure substantially higher reimbursements. To illustrate, the day after such a conversion, the new “hospital” entity (same patient, same location, same surgeons, same staff, same facility costs) receives $960 for cataract surgery, compared to the $1,749 it was paid the day before when it was an ASC. This makes no sense.

In a quest to achieve budget savings and address myriad federal deficit issues — and, indeed, perhaps pay for the SGR fix — Congress is looking for new ideas to generate significant Medicare savings. And, with hospitals accounting for the lion’s share of program expenditures, Washington policy wonks are looking in places heretofore off limits. In its recently released Report to Congress, MedPAC delivered some far-reaching and unprecedented options to the budget scalpers on Capitol Hill. The Commission is guided by three principles: (1) patients should have access to all appropriate settings; (2) a prudent purchaser should not pay more for the same service in alternate settings; and, (3) Medicare should base its rates on the resources needed to treat patients in the lowest cost, clinically appropriate setting.

How do these principles translate into policy and payments? MedPAC is advocating that HOPDs be paid at the ASC rates (which, as noted above, is about 40% lower than current hospital payments) for services: (1) that are furnished in ASCs more than half the time; (2) that are infrequently provided with an emergency room visit; and, (3) where patient severity in the HOPD is no greater than in the ASC. Most high-volume eye surgeries would meet these parameters. Will Congress take the plunge and adopt this proposal? Time will tell, but the approach is being seriously considered on Capitol Hill.

Why should ASCs care about this development when our rates might not be increased? There are a number of reasons for an enthusiastic embrace of such a proposal by the ophthalmic ASC community. First, services will undoubtedly migrate from the HOPD to surgery centers — many hospitals are less than enamored about ophthalmic surgery and this concern would be heightened if hospital payment rates are substantially reduced. Second, the wide disparity in payments to HOPDs and ASCs would be significantly narrowed. Third, the fact that ASCs and hospitals would be reimbursed at the same rate for many procedures solidifies our case that our centers should receive the same annual update. And, importantly, ASCs and hospitals would have identical interests in lobbying for higher payments, allowing surgery centers to ride the coattails of the gargantuan hospital lobbying forces. All in all, were Congress to adopt this MedPAC recommendation, the increase in revenues to ASCs from the expanded volume of cataract, vitreoretinal and other cases likely would be substantial.

Michael Romansky, JD, is a senior lobbyist and vice president of corporate development for the Outpatient Ophthalmic Surgery Society.
Group Purchasing Perspectives

Learn about the options and assistance available to you from varying viewpoints.

Are you getting the best prices on your supplies and equipment? It’s difficult to know the answer. You might be negotiating one-on-one with a supplier or sifting through the relative merits of various group purchasing organizations (GPOs). Certainly you’re cultivating relationships with representatives of major ophthalmic supply and device manufacturers and pharmaceutical companies.

Could you be doing better?

A Little Background on GPOs

The answer isn’t cut and dried, but it starts with understanding your options. GPOs have undergone some changes from the ASC perspective. Their original intent was to serve hospitals by setting up contracts with large manufacturers at reduced rates based on volume and commitment. The GPO passed along the savings and convenience of one-stop shopping to its members. As GPOs began to serve other facilities, ASCs could join a GPO but they didn’t get the benefit of aggressive hospital pricing due to their comparatively smaller purchasing volumes.

As GPO rates for ASCs and hospitals became comparable, ASC use of GPOs increased.
However, GPOs limited ASCs to one exclusive contract. These limitations proved challenging, but finally, ASCs were permitted to join as many GPOs as they liked. Now administrators are able to compare GPOs, choose one or more that meet their needs and apply to join them.

GPOs are just one of several options available to ASCs to reduce spending through group purchasing. Other options may depend on the size of your business, your purchasing preferences and the support you receive from suppliers and professional groups. To get a clearer picture, consider these varying perspectives on the subject.

**Multi-ASC Purchasing**
Companies with multiple ASCs obviously use a high volume of supplies and therefore have excellent leverage for purchasing them. Still, they may be able to obtain even better pricing and convenience by using GPOs.

Lou Sheffler is co-founder of American SurgiSite Centers and Chief Operating Officer responsible for all clinical operations of multiple outpatient surgical centers in the northeastern United States. He uses GPOs for specific purchases. “It works in the same way that consumer shopping does. You might join Costco and use it to buy items such as bulk paper towels, but you’d go to a smaller market with a larger selection to find an exotic spice,” Sheffler explains. “Similarly, through a GPO, we buy common general medical supplies such as syringes, disinfectants, sterilizing wraps, gowns, gloves and masks that are used by all medical subspecialties. Some GPOs also handle medications and anesthesia. It’s worthwhile to join a GPO for pricing and one-stop shopping on general supplies. And we can reduce prices even further if we’re willing to show loyalty to a vendor and sign a contract that covers several years.”

Sheffler doesn’t use GPOs for specialized ophthalmic products. For example, IOLs, phaco tips and viscoelastics for cataract surgery require a different approach. “For ophthalmic surgery supplies, we’re better off dealing directly with companies such as Alcon, AMO and Bausch + Lomb and creating competition between them for comparable products and better pricing.”

**Single-ASC Purchasing**
Administrators working at a single ASC don’t always find group purchasing to be the best financial solution. As Director of Business and Financial Development for San Antonio Eye Center and Executive Director of South Texas Total Eye Care, Albert Castillo supports the work of 41 surgeons. “For a single ophthalmic ASC, there aren’t many resources for group purchasing. We get better prices for medical supplies such as gowns, drapes, blankets and IV tubing by shopping around online,” he explains.

Castillo also finds that he can negotiate the best price for equipment by shopping different vendors instead of sticking to one. Castillo is the Members Services Consultant for the Outpatient Ophthalmic Surgery Society (OOSS). He and other OOSS members reach out to colleagues to discuss negotiation tactics and pricing. OOSS itself offers a benchmarking platform that Castillo uses to track and compare his costs.

“It’s worthwhile to join a GPO for pricing and one-stop-shopping on general supplies. And we can reduce prices even further if we’re willing to show loyalty to a vendor and sign a contract that covers several years.”

— Lou Sheffler is co-founder of American SurgiSite Centers and COO

“Multi-ASC Purchasing”

“A little compromise by surgeons can save money as well, according to Castillo. After all, every physician has different preferences, and that can make supply orders very complicated. “Within our ASC, we used the OOSS benchmarking tool to see our cost per cataract case compared to the average OOSS member. We’ve broken it down further to see the cost per cataract surgeon and found a range of nearly $200,” he recalls. “The range was so large because surgeons were using different supplies, so we got all of our surgeons together and we standardized everything, such as pre- and post-op instructions, medical supplies, IOLs, instruments, scheduling, consents and medications. Today, our cataract costs...
per procedure are within $10 for all doctors. The compromise simplified purchasing, and most importantly, it helped us control the cost per case. While we do allow for some exceptions, having a baseline standard for all physicians also makes ordering easier on the staff, improves efficiency and the patient experience.”

**Major Distributor**

If you want to participate in a GPO, you can do so through the GPO itself or through distributors that work with a specific GPO. Bill Barr, Vice President of Healthcare Services at Henry Schein, Inc., (henryschein.com), explains that distributors drive savings in several ways, one of which is the use of a GPO strategy. The goal is to find the right purchasing program and combine it with the company’s portfolio of products and services to provide a “best-in-class” program.

“We work with the five major GPOs and several key affiliates. The GPOs develop membership rosters and negotiate contracts with manufacturers. As the world’s largest distributor to office-based practitioners, we access those contracts and sell to our clients,” Barr says. “There are additional types of strategies for driving savings, including bulk buying and tier access, in which we evaluate what a practice needs and perhaps aggregate volumes and spending to facilitate greater savings from a manufacturer. Working with a distributor partner allows clients to understand what programs are available to meet their needs. When designing and participating in a program, volume isn’t always king. Many programs are about commitment and I tend to favor committed programs because they allow us to meet the objectives that we define for a specific manufacturer, facilitating better contracting and pricing for the clinician.”

Barr looks at a new customer’s supply purchases in terms of choices and volume, and then helps that customer develop an efficient and economical plan.

**You Have Supplies — Now Get an Inventory System**

Obtaining good group pricing is beneficial, but even greater economic advantages lie in carefully controlling your inventory, according to Lou Sheffler, co-founder and Chief Operating Officer of American SurgiSite Centers.

“We negotiate supply prices with outside entities, but inventory is a more critical internal factor and is up to you to manage,” he says. “The goal is to turn over inventory quickly — optimally once or twice a month — and tie up as little money as possible in items that sit on your shelves. Many people don’t realize that unlike doctors’ offices, ASCs spend more money on supplies than personnel. Supplies determine how much money you have in the bank and how profitably you run the business. You can’t save money on personnel, but you can play around with supplies if you have good information about pricing and inventory levels.

American SurgiSite Centers invested in an inventory management system to improve turnover and liquidity.

“We have nine surgery centers, where we handle about 60,000 eye surgeries a year. About 25% of our income goes to medical supplies, which means we’d better get supplies at the right price and we’d better control our stock. We’d be crazy not to use an inventory system,” Sheffler points out. “Before the inventory system, we were horribly overstocked. The clinical employees were afraid of running out of supplies, so they tended to overbuy to feel safe. Investing in an inventory system saved us a great deal of money. In a single surgery center, we managed to drop the shelved investment in the supply room from $200,000 to $100,000.”

Sheffler recommends that practices include inventory in the responsibilities of an administrative employee and allow clinical employees to focus on clinical work. With an inventory system, every medical supply has a barcode that is scanned by the employee who unpacks and shelves it. The scans tell the system how much you have on the shelves. Staff members scan items removed from the shelves as well, and the software reminds them when it’s time to reorder based on the desired stock level you’ve previously assigned. The system creates a reorder report and a staff member simply has to click a button to place the order.

“Even if you have a small ASC, you can use the electronic ordering systems provided by many of the large suppliers,” Sheffler says. “The alternative is to leave too much money tied up in inventory while your staff goes around checking shelves with a notebook, which also gives you no data about usage and spending. You need an inventory system.”

“We meet people in ophthalmology who are very savvy with regard to purchasing, as well as others who are seeking help in this area,” says Barr. “As their partner, we identify ways to drive savings through group purchasing, but we also offer solutions that help the practice run more efficiently and profitably in...
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this new age of health care. That might mean identifying the GPOs that sell the product mix a practice uses, comparing the advantages, negotiating a bulk buy, or even identifying products sold directly from the manufacturer that we can help them purchase as a liaison for a better price. There are many programs out there, and by walking them through the options, we maximize the savings for each individual facility.”

According to Barr, taking on the role of trusted advisor also means providing clients a transparent approach to programs being offered in this cost-conscious market.

**GPOs and ACA Sunshine Laws**

Did you know that the Physician Payments Sunshine Act in the Affordable Care Act (ACA) applies to physician payments from GPOs? Here are some quick facts.

The purpose of the Sunshine Act is to increase transparency surrounding certain physician arrangements. While GPOs can provide supplies at a reduced rate, they also charge administrative fees and other fees as part of their business. This raises questions as to whether those fees are reasonable, and who is receiving them. The Sunshine Act brings transparency to certain payments or other arrangements between GPOs and physicians. By way of example, ASCs are often run and led by physicians; if these same physicians are involved in setting up contracts with a GPO, that may raise concerns as a potential conflict of interest.

It only affects you if a GPO pays you. Just as in the case of manufacturers, GPOs must report certain payments they make to physicians. That might be payment for a consulting arrangement, speaking engagement, conference attendance, research or other interaction that results in a transfer of value. If you do receive money or other value from a GPO, you may want to have a system in place to document it and double check that your payment from that GPO reflects fair market value.

State laws still apply. If you live in Minnesota, Massachusetts or Vermont, you’ve already been subjected to the sunshine laws in those states. Some of those state’s specific provisions may still be relevant, even now with federal laws in place. For example, the federal law doesn’t have a gift ban, but if your state has one, the ban will still apply.

Watch this in 2015. One of the provisions of these laws was the creation of a database — Open Payments — to include information about payments received by physicians from industry. The first reported database covered the period August 2013 through Dec. 31, 2013. Its release was less than incident-free in September 2014.

At the end of June 2015, data covering calendar year 2014 will be released. One concern about the release of this data is the potential to trigger enforcement activity, either through government data mining or whistleblower activity. In addition, because this program requires the submission of information to the government, the government may, in turn, opt to audit manufacturers or GPOs to ensure the data submitted is accurate and complete. Failure to provide accurate and complete information may trigger financial sanctions against the manufacturer or GPO up to $1.1 million.

Source: Abraham Gitterman, Arnold & Porter LLP in Washington, DC.

“In today’s web-based environment, many websites offer opportunities to save 20% to 30%. That isn’t practical, and it’s impossible for them to support that claim without knowing exactly what you’re going to purchase. The market has driven competition among distributors and manufacturers, so such a dramatic spending cut isn’t likely,” Barr says. “As part of our partnership, we dive deep to determine what a client is currently paying and explore their genuine potential savings.”

**Eye Care GPO**

Although many GPOs offer only general medical supplies, it’s possible to purchase ophthalmic-specific products through some of them. The Alliance (thealliance bg.com) is a GPO that began as an optical buying group focused on dispensary fulfillment. When the GPO aligned with its parent company, Surgery Partners, it expanded to include the supply needs of eye care practices and ophthalmic ASCs.

“Alliance is unique in that we’re the only optical buying group with a med-surg GPO. We have about 300 ophthalmologists in our med-surg program,” says Kim Bratcher, Operations Manager at The Alliance in Monmouth, Ill. “We’re affiliated with MedAssets, which has relationships encompassing about 22,000 manufacturer contacts. Our core business is eye care, and through our optical offerings and MedAssets, we deliver basic surgical needs and eye care-specific supplies. The MedAssets affiliation even allows us, in some cases, to piggyback clients onto major hospital contracts for even lower pricing.”

The Alliance also has a pharmaceutical affiliation with a distributor named CuraScript (curascript.com). According to Bratcher, this is the final
BUYING POWER | OASC

including staff education, video tutorials, recorded webinars, internal marketing tools, messaging for the referral network, press release samples and radio/TV scripts, some of which are available through an online self-service portal. We also help in making sure all of the right forms, such as ABNs and informed consent, are in place,” says Clayton of Richens Eye Center. “They’ve seen many practices implement the technology, so they know the good ideas and the bad,” he says regarding Sightpath.

The mobile option was really the only option for us when we considered the total overhead of a femto purchase. It gave us the ability to introduce the new technology to our patient population without the need for a patient volume that we felt was unattainable right out of the gate.”
— Kelly Clayton, Practice Administrator, Richens Eye Center in St. George, Utah

A Durable Solution
Neither Clayton nor Dr. Starkey rules out the possibility that their practices will eventually buy their own lasers, but for now, they’re happy with the mobile option. “ForTec has been great to work with, and the machine has worked impeccably for me,” Dr. Starkey says.

Clayton estimated that 23 cases per month would be the break-even point for Richens Eye Center if it were to purchase a laser. At the end of last year, they were averaging right around that number, and expect to exceed it in 2015. “But we like the Sightpath model and feel the laser technician is a real bonus in that he provides experience and skill. Also, why aim for just slightly above breaking even when considering a purchase option? If Sightpath has the ability to provide us more days in the future, I’m not sure it makes sense to purchase a laser unless the cost to purchase drops significantly.”

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piece of a one-stop shopping relationship with eye care practices and ophthalmic ASCs.

“We take eye care clients from the dispensary to surgery. They can source everything they need. Cataract packs are an exception because although we can source them, IOL manufacturers specialize in cataract pack pricing, so we recommend that most clients buy through the manufacturer for the best price,” she says.

Bratcher reviews clients’ supplier or inventory lists, comparing their current spending on consumables and pharmaceuticals with the costs for members of The Alliance. The result is a list of alternatives. Some members choose The Alliance for all of their needs, while others choose relevant components.

In one final tip for saving money, Bratcher notes the member might save money using non-branded products. “Doctors might prefer a specific brand of certain products and have no preference for others,” she explains. “If doctors elect to use quality non-branded products for some of their purchases, they can decrease costs even more.”

OOSS Initiatives
OOSS has several initiatives under way to address supply management considerations.

“Our benchmarking program, with consulting support from Albert Castillo, enables members to track and compare supply costs over time and identify ways to improve their results,” says Kent Jackson, PhD, Executive Director of OOSS. “Given supplies can represent 25% or more of the total cost of operating an ophthalmic ASC, our members are keenly focused on how to acquire the best and most affordable prod-

OOSS Initiatives

CONTINUED ON PAGE 21
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Use OMIDRIA with caution in individuals who have previously exhibited sensitivities to acetylsalicylic acid, phenylacetic acid derivatives, and other non-steroidal anti-inflammatories (NSAIDs), or have a past medical history of asthma.

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Refer to the Directions for Use and Operator’s Manual for a complete listing of indications, warnings, cautions and notes.

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Doctors might prefer a specific brand of certain products and have no preference for others. If doctors elect to use quality non-branded products for some of their purchases, they can decrease costs even more.”

— Kim Bratcher, Operations Manager at The Alliance in Monmouth, Ill

According to Dr. Jackson, “Our OOSS Advantage initiative includes development of a directory that features an ever-widening range of industry partners that value the work of OOSS and offer products and services of particular interest to our members. In the process, some partners are choosing to offer advantaged pricing and/or other value-added services and resources to our members as preferred business customers.”

The future of OOSS Advantage, as described by Dr. Jackson, “…includes exploration of the full range of products and services that are most valuable to our member centers and the providers and buying groups like The Alliance and Henry Schein that serve the interests of both.

“That’s the next step. Once we identify individual providers and buying groups that serve our membership locally, regionally and nationally, we can approach them on behalf of our members,” Dr. Jackson explains. “A final piece will be to share insights and best practices for purchasing, negotiating and managing supplies through member networks and educational programming.”

It’s clear that when making purchasing decisions, you have the support of colleagues, professional groups such as OOSS, supply distributors and GPOs, and others. When combined with your own business knowledge, you can feel confident that your purchasing decisions are sound.
Glaucoma Drainage Surgery: Still Viable for the ASC?

Medicare reimbursement for tube shunt procedures has been reduced significantly.

As of Jan. 1, 2015, when a tube shunt procedure is performed with a patch graft, the providers can no longer bill using both CPT 66180 for the aqueous shunt procedure and CPT 67255 for scleral reinforcement. Instead, under the new American Medical Association (AMA) CPT coding instructions, 66180 describes both aspects of the surgery (aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft). “The net effect of this consolidation of two codes, 66180 and 67255, into a single code results in reduced payment: 31% lower for the surgeon and 20% lower for the facility — ASC or hospital outpatient department (HOPD),” says Kevin J. Corcoran, COE, CPC, CPMA, FNAO, president of Corcoran Consulting Group.

As Corcoran explains, prior to this change, the 2014 national ASC payment amount for 66180 was, rounded to the nearest dollar, $1,678, and the national ASC payment amount for the secondary procedure, 67255, was $474, for a total of $2,152. The 2015 national ASC payment amount for 66180 is $1,712. The 2014 Medicare surgeon reimbursement for tube shunt surgery was $1,214 for 66180 and $447 for 67255 for a total of $1,661. In 2015, the surgeon can bill only one code, 66180, for the shunt and the graft, and Medicare payment is $1,152. Coding and reimbursement for tube shunt revision procedures have been changed in a similar fashion. The patch graft can no longer be billed separately with 67255, and the previous code for revision, 66185, is now used for both the revision and the graft. “Again, the

By Desiree’ Ifft, Contributing Editor
I CHOOSE EXPERIENCE.

Edward Stack, MD
Michigan Vision Institute

“It’s easy to see that Sightpath has been doing this for a long time. I don’t have to worry that something isn’t going to be at the case day. There is always a back up to the equipment. I know my day is going to be a lot easier when Sightpath is on board.”

Hear more from Dr. Stack at sightpathmedical.com/ASC

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Offering variable access to equipment and services for traditional cataract, laser-assisted cataract and refractive surgery.
net result is a reduction in reimbursement: 34% lower for the surgeon and 55% lower for the facility," Corcoran says. Although it’s less frequent, a surgeon can perform a tube shunt surgery without a patch graft. The applicable 2015 codes are 66179 (shunt without graft) and 66184 (revision without graft). "Further, the providers can’t use 66179 or 66184 along with the old patch graft code, 67255," Corcoran cautions. "In all of these tube shunt scenarios, the bottom line is there is now only one code."

The rationale for the changes? Corcoran says, “AMA asked the American Academy of Ophthalmology to look at these codes, with a little bit of prompting from the Centers for Medicare & Medicaid Services (CMS), and recommend new code descriptors to address the ‘separate procedure’ limitation that was generally ignored during claims processing. Significantly, CMS never issued any constraints within its National Correct Coding Initiative to address this issue, so the Medicare Administrative Contractors always paid these claims for concurrent procedures.”

**Crunching the Numbers**

The decrease in reimbursement has ASCs across the country taking a close look at how they need to react. “We have to adapt somehow,” says Frank Cotter, MD, a glaucoma and cataract surgeon with Vistar Eye Center in Virginia and co-owner of the Roanoke Valley Center for Sight, an ASC. According to his team’s initial review of their center’s numbers, in 2014 their costs per tube shunt case including supplies and overhead were $673 for 66180 and $765 for 67255 (Totaling $1,438). In 2014, they were reimbursed a total of $2,065. For the same procedure with the same costs in 2015, the total reimbursement is $1,646.

Currently, Dr. Cotter performs all of his tube shunt surgeries at the ASC but he isn’t sure he can continue to do so in light of the reimbursement change. “It just may not be affordable now,” he says. “Essentially, we’re no longer being reimbursed for the patch graft, something we need to use. Tube shunt surgery was already the least profitable procedure performed in our ASC. It’s hard to understand why reimbursement is being reduced further for a complex procedure performed on patients who are facing irreversible blindness.”

Dr. Cotter estimates that 40% of the glaucoma surgeries he performs are tube shunts with patch grafts and 60% are filtration procedures, i.e., trabeculectomies and MIGS devices.

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**Tips for Efficiency**

Averag operative time for glaucoma surgeries is slightly longer than for cataract surgeries, but when it comes to performing procedures in the ASC, glaucoma surgeons can’t afford to be any less focused than their cataract colleagues on creating efficiencies. Many are currently re-evaluating whether they can take any additional steps to streamline tube shunt procedures to counteract the elimination of the CPT code for a patch graft and associated reduction in reimbursement that took effect Jan. 1, 2015.

“Given the familiarity of the staff with the procedure and the fast OR turnover time, we’re already efficient when we operate in the ASC,” says Annette Sims, MD. These are some of the other ways she keeps procedures economical at the Oregon Eye Surgery Center in Eugene:

- Most important for me is having a qualified and experienced surgical assistant who is adept at the necessary tasks such as handling tissue and cutting sutures and who also knows what my needs are during the procedure. Being able to anticipate my next move, what instrument I need or what suture I’m going to want loaded before I ask, cuts down on overall case time.

- Performing the steps of the procedure the same way and in the same sequence every time and not varying the instruments used from case to case help the support staff to anticipate my next movement.

- I try to minimize supplies and sutures. If I use a corneal traction suture at the start of a case, I can use that same suture to close the conjunctiva at the end of the case.

- Purchasing extra instruments may seem like an extra cost, but it can be an investment. For example, we have two glaucoma trays that are fully outfitted for glaucoma surgeries. We’ve found that scheduling glaucoma surgeries back to back is more efficient because the surgical staff gets in a groove. The cases tend to run more smoothly, and we can do this because we are not waiting for instruments to be cleaned.

- Being verbal in the OR. Often, I’ll pause and say my next few steps out loud, which serves to keep everyone in the room focused on the task at hand and can be especially helpful in bringing new surgical staff up to speed.

- I use a patch graft that doesn’t need much preparation or manipulation during the case. For example, I use a corneal patch graft prepared from the eye bank that is already cut in half and is of half thickness.
Glaucoma Surgery Trends

According to Kevin J. Corcoran, COE, president of Corcoran Consulting Group, use of tube shunts for glaucoma surgery is rising slightly while the number of trabeculectomies performed is diminishing only slightly more. Medicare paid for the following:

Aqueous shunts (CPT 66180)
- 11,111 in 2011
- 12,021 in 2012
- 12,835 in 2013 (most recent data available)

Trabeculectomies (CPT 66170 regular and CPT 66172 complex)
- 19,194 in 2011
- 18,007 in 2012
- 17,729 in 2013 (most recent data available)

An earlier analysis of Medicare claims data by Corcoran showed the number of tube shunt procedures paid for by Medicare rising by 184% from 1995 to 2004 and the number of trabeculectomies in the same time period decreasing by 53%.1

In the meantime, the types of surgical procedures performed for the treatment of glaucoma has diversified, but a surprising trend has emerged: In totality, the number of glaucoma procedures performed is not increasing. Medicare paid for:

Total number of glaucoma surgeries, including laser procedures:
- 355,277 in 2011
- 354,868 in 2012
- 365,325 in 2013 (most recent data available)

“Although the total number of surgeries for glaucoma is flat,” Corcoran says, “no one is sure why.” His most recent analysis of Medicare claims data related to glaucoma surgery will be published soon in the American Journal of Ophthalmology.

REFERENCE

Potential Next Steps

“One possibility for addressing the shortfall is for surgeons to shift tube shunt procedures from the ASC back to the hospital, where reimbursement rates are still higher than in ASCs,” Dr. Cotter continues. “It’s puzzling why CMS would want to drive patients in that direction.” Certainly, Dr. Cotter would prefer to keep the procedures at the ASC, where the staff members are experienced in ophthalmology, OR turnover time is much faster, and the whole experience, including cost, is better for patients. “The efficiency of the ASC helps me to manage my day better as well,” he notes. “Turnover time is 5 minutes. We have no wasted steps during the procedure because this staff has assisted in more than 1,000 shunts with me. Compared to working at the hospital, I can perform twice as many cases in the ASC per day. That gives me more time to provide care in the clinic. It also helps with my personal bottom line because I can accomplish more in the course of a day.”

Another potential response to the decline in reimbursement, Dr. Cotter suggests, is for surgeons to further explore or revisit alternative surgical techniques that eliminate the need for a patch graft.1-4 He points to one study in which Ahmed valves were implanted in more than 100 children through a needle-generated scleral tunnel. No graft was used, yet no tube extrusions or exposures occurred.1 He cites another study, out of Wills Eye Hospital, which showed that an autologous scleral lamellar graft can be effective at preventing tube erosion and graft-related or intraocular complications.3

“We don’t know at this point if these would be workable solutions, but they’re worth considering if they allow us to continue performing tube shunt surgeries in the ASC,” Dr. Cotter concludes. “We can try to increase our efficiency (See “Tips for Efficiency”) but in the end, there’s no magic to this — if we aren’t reimbursed at least a minimum amount for services provided, we can’t be profitable.”

References
We often emphasize that as we become better surgeons and perform higher volumes of surgery, we obtain better outcomes. We also encounter fewer complications, primarily because we anticipate problems prior to surgery. However, it’s still imperative that we’re prepared to change gears at the first sign of any complications to limit both the stage of complication and the collateral damage. Preparation and planning are the keys to successful outcomes.

**Anticipate Problems**

The best way to prevent complications is to identify the potential causes in advance. For example, when a patient has asymmetric anterior chambers, I consider padding the surgery schedule because I know there may be zonular issues, which may increase the length of time required to complete the procedure. I also know there’s a greater chance patients will require vitrectomy if they have unilateral shallow chambers, pseudoxfoliation syndrome, loose lenses, post-traumatic cataract, cataract complications in the fellow eye or had prior vitrectomy surgery.

Preoperative surgical planning for these patients is important. I classify the case as having a higher level of difficulty, place it at the end of a long line of routine cases, consider peribulbar anesthesia and always keep vitrectomy instrumentation on standby. Preventive measures during surgery include recognizing zonular laxity, avoiding convexity of the lens dome, re-grasping the edge often to control the vector of tear, burping the bag to prevent tamponade of continuous curvilinear capsulorrhexis (CCC), maintaining nucleus mobility, respecting zonules during rotation, staying in the “safe zone” within the rhexis with the phaco tip and knowing where that CCC edge is at all times.

**Recognize Early Signs**

When performing repetitive cataract surgeries, you may slip into a comfortable, almost Zen-like state but each patient’s tissue and circumstances are different, so it’s necessary to be alert and observant at all times. Vigilance means problems will be detected and addressed early to help ensure the best outcome possible.

To stay focused, it helps to start with a quiet environment or soothing music in the OR. I invite each patient’s family to watch the surgery remotely through the microscope, and I explain what I’m doing to the patient and family throughout the procedure with a specific dialogue designed to inform and reassure. When I operate on 25 patients a day, I talk a great deal, but it keeps the patient calm, it keeps me focused, and it allows my scrub nurse, circulator and other staff to stay abreast of our progress.

If something unusual happens — I detect a little spidering of the capsule during phaco, for example — I say, “timing,” and then my staff knows it’s an atypical case. If I weren’t focused, I might miss that spidering or other subtle sign, miss the opportunity to use viscoelastic to stabilize the chamber, or continue with aspiration or phaco that would encourage vitreous prolapse and cause vitreoretinal traction.

**Prepare Your OR**

Before surgery, we usually know which cases will be challenging, but even straightforward cases sometimes surprise us. Therefore, we must be prepared in the OR. I suggest that surgeons use a mental flowchart.
approach to plan their strategies. For example, you might have in mind, “If there is iris prolapse, then perform steps a, b and c….” The flowchart should include steps you need to take, as well as instructions you need to give your staff so they can help you make the surgery a success.

A good way to initiate that plan in the OR is to call a “Code V.” Physicians use a code red or blue for emergencies, and it’s wise to prepare for a response to vitreous loss in the same way.

At the end of the day, after the last patient is wheeled out, randomly call a Code V and respond with your staff. They should know the location of the vitrectomy kit, know its setup and parameters and be ready with all of the other items you need at your disposal for the best outcome. You can use the Code V drills as an opportunity to practice your own timing and sequencing with the vitrectomy foot pedal.

Consider This Case
My first attempt at using the femto-second laser for intumescent cataract was a difficult one. The patient was uninsured and the cataract had been profound for some time, to the point of becoming morgagnian. After ensuring the patient had a clear understanding of her poor prognosis, we proceeded.

Despite increasing femto parameters according to best advice at the time and a mere 1.5 second capsulotomy, on the table, I encountered an anterior chamber clouded with lens milk and, despite OVD and trypan blue staining, had to tap to find whether and where the capsule was perforated. For the first time in years, I defaulted to an extracapsular extraction as it was clear I didn’t have a complete capsulotomy and it was difficult to identify the integrity of the posterior capsule with this huge, free-floating, dense chip of a nucleus.

The patient required a limited anterior vitrectomy. Because she had a poor visual prognosis and experienced unexpected bleeding from the root of the iris during our surgical maneuvers, I left the eye aphakic. Postoperatively, a central retinal vein occlusion was diagnosed leading to cryotherapy and laser treatments for neovascularization. As there was no central potential for vision improvement, a secondary implant was never indicated and the eye healed uneventfully.

Even in this very rare situation, my focus and preparation as well as an informed staff helped me successfully complete this patient’s surgery under difficult circumstances.

The 10 Commandments of Anterior Vitrectomy

1. Thou shalt not lose focus during surgery. Early detection means limited damage.
2. Thou shalt not allow the chamber to collapse after capsule rupture. Vitreous flows from a high to a lower pressure gradient.
3. Thou shalt not allow an open system during or after surgery. Instead, use a biaxial vitrectomy technique with irrigation anteriorly and vitrector through a tight paracentesis or pars plana incision. Keep the globe formed with OVD and with closed incisions or a scleral plug to maintain normal tension.
4. Thou shalt not irrigate, displace or fish through the vitreous. Instead, if the nucleus is below the posterior capsule, refer the patient for 3-port vitrectomy.
5. Thou shalt not fail to identify vitreous presentation. Perform preservative-free triamcinolone acetonide particulate staining after OVD removal. Instill as a last maneuver.
6. Thou shalt not aspirate vitreous with phaco or irrigation and aspiration (I&A). Instead, compartmentalize the vitreous and lens fragments and remove the cortex either dry (syringe with no irrigation under OVD control) with the vitrector on I&A-cut or bimanual I&A.
7. Thou shalt not sponge or sweep vitreous from the wound. Traction on the vitreous will cause a retinal tear. All complicated patients deserve a timely scleral indented retinal exam.
8. Thou shalt not fail to understand vitrectomy settings. You will always be cutting while aspirating. Use the highest cut rate available and the lowest effective flow and vacuum (not linear). The bottle must be balanced to maintain normal tension.
9. Thou shalt not purposely violate both the anterior and posterior capsules. Destruction of the CCC results in loss of the ability to optic capture a potentially unstable IOL. Instead, enlarge with a radial cut and a spiral tear rather than relaxing incisions.
10. Thou shalt not fail to provide aggressive antibiotic prophylaxis. A ruptured capsule dramatically increases endophthalmitis risk. Consider intracameral antibiotics, even for routine cases (off label), and also give a single oral dose of a fourth-generation fluoroquinolone when complications occur.
Ophthalmic ASCs have had just over 2 years to adjust to tighter regulation and monitoring of medications compounded for their patients. That adjustment typically focuses in two areas. First, most ASCs and practices now purchase their compounded medications from an outside compounding pharmacy. The added complexity and cost of preparing medications under the guidelines spelled out in Chapter 797 of the US Pharmacopeia (USP 797) — which is required by Medicare and an increasing number of states — makes onsite compounding impractical for most facilities. The USP 797 guidelines have been in place since 2008, but weren’t proactively enforced in ASCs until late 2012.

Second, each compounded drug must be prepared from a prescription for a specific patient. Practices can no longer stock batches of compounded medications to use as the need arises. The single-patient requirement creates lag time between ordering the medication and treating the patient and this may create dangerous delays in emergency care.

“In the past, surgery center staff mixed up a batch of their block solution and drew up doses for each patient under aseptic conditions at

How ASCs Have Adjusted to Stricter Compounding Rules

Most order from outside pharmacies, but how to handle emergency cases remains unresolved.

By James Knaub, Contributing Editor

The Alcon suite of diagnostic technologies has been designed to help surgeons minimize errors throughout the entire procedure for maximized cataract refractive outcomes and ATIOL predictability:

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Streamlines data calculation and communicates planning seamlessly to your LenSx® Laser and/or surgical microscope to help you make the right clinical decisions.

**ORA™ System with VerifEye+™ Technology**
Delivers real-time validation to help you make better-informed clinical decisions in the OR and reduce the number of patients who fall outside the intended astigmatic target by more than 50%.†,1

† Intended target is defined as within 0.5 D of targeted astigmatism.
1. Alcon data on file.
VERION™ REFERENCE UNIT AND VERION™ DIGITAL MARKER IMPORTANT PRODUCT INFORMATION

CAUTION: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

INTENDED USE: The VERION™ Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient’s eye in order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION™ Reference Unit provides surgical planning functions that utilize the reference image and preoperative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION™ Reference Unit also supports the export of the high-resolution reference image, preoperative measurement data, and surgical plans for use with the VERION™ Digital Marker and other compatible devices through the use of a USB memory stick. The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician’s microscope view.

CONTRAINdications: The following conditions may affect the accuracy of surgical plans prepared with the VERION™ Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements. Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit. The following contraindications may affect the proper functioning of the VERION™ Digital Marker: changes in a patient’s eye between preoperative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or blurred conjunctiva due to anesthetics). In addition, the use of eye drops that contain sclera vessels before or during surgery should be avoided.

WARNINGS: Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker. Only use the provided medical power supplies and data communication cable. The power supplies for the VERION™ Reference Unit and the VERION™ Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on. Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system. The VERION™ Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONs: To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION™ Reference Unit and the VERION™ Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings, and precautions.

ORA™ SYSTEM IMPORTANT PRODUCT INFORMATION

CAUTION: Federal (USA) law restricts this device to sale by, or on the order of, a physician.

INTENDED USE: The ORA™ System uses wavefront aberrometry data in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

CONTRAINdications: The ORA™ System is contraindicated for patients:• who have progressive retinal pathology such as diabetic retinopathy, macular degeneration, or any other pathology that the physician deems would interfere with patient fixation;• who have corneal pathology such as Fuchs’, EBMD, keratoconus, advanced pterygium/pairing the cornea, or any other pathology that the physician deems would interfere with the measurement process;• whose preoperative regimen includes residual vasoactive substances left on the corneal surface such as lidocaine gel or viscoelastic;• with visually significant media opacity (such as prominent floaters or asteroid hyalosis) what will either limit or prohibit the measurement process; or• who have received retro or peribulbar block or any other treatment that impairs their ability to visualize the fixation light.

In addition, utilization of iris hooks during an ORA™ System image capture is contraindicated, because the use of iris hooks will yield inaccurate measurements.

WARNINGS and PRECAUTIONs:• Significant central corneal irregularities resulting in higher order aberrations might yield inaccurate refractive measurements. • Post refractive keratectomy eyes might yield inaccurate refractive measurements. • The safety and effectiveness of using the data from the ORA™ System have not been established for determining treatments involving higher order aberrations of the eye such as astigmatism and spherical aberrations. • The ORA™ System is intended for use by qualified health personnel only. • Improper use of this device may result in exposure to dangerous voltage or hazardous laser-like radiation exposure. • Do not operate the ORA™ System in the presence of flammable anesthetics or volatile solvents such as alcohol or benzene, or in locations that present an explosion hazard.

ATTENTION: Refer to the ORA™ System Operator’s Manual for a complete description of proper use and maintenance of the ORA™ System, as well as a complete list of contraindications, warnings and precautions.

the beginning of the day,” says Crissy Benze, RN, BSN, a consultant with Southern California-based Progressive Surgical Solutions. “You can’t prepare doses for the whole day anymore.”

NECC Repercussions

The demarcation point between the past and now — as it pertains to compounding medications — was the tragic incident involving the New England Compounding Center (NECC). In 2012, a few batches of tainted medications triggered a fungal meningitis outbreak that led to 64 deaths. Both the owner and chief pharmacist of the now-bankrupt pharmacy were charged with racketeering and second-degree murder this past December. The NECC incident prompted investigation, legislation, regulation and tighter enforcement of medication compounding on both the federal and state levels. Before the NECC incident, pharmacies tended to be inspected only when complaints were made. Investigations prompted by the NECC case found lax compliance and enforcement of existing regulations was common in the compounding industry. The FDA and state pharmacy boards began increasing proactive inspections. For example, surprise state inspections in Massachusetts, where the NECC was located, found that only four of 40 compounding pharmacies investigated passed the safety inspection; 11 pharmacies were partially or completely shut down.

Because the problem wasn’t limited to Massachusetts, the investigations resulted in the federal Drug Quality and Security Act of 2013, which granted additional authority for FDA oversight of compounding. Numerous state legislatures added new laws and pharmacy boards have tightened their regulation and enforcement. In 2013, 10 states passed new laws regarding compounding.

“What happened at NECC scared everyone,” says Todd Albertz, Director of Surgical and Pharmacy Services at Cincinnati Eye Institute, which has offices in the tri-state area of Ohio, Kentucky and Indiana. “Everyone wants to make sure that what they’re injecting into the eye is the right medication and was properly prepared. Before, the issue wasn’t on anybody’s radar. Now, at every meeting I attend, this issue is front and center. You can either set up your own compounding pharmacy, as we have, or you can buy everything from an outside compounding pharmacy. Both approaches are expensive, but required.

“We’ve addressed the compounding issue and the patient-specific issue by bringing it in house, but most practices aren’t equipped for that,” Albertz adds. “Because of our large size, we were able to do it.” CEI has the case volume to make setting up its own compounding pharmacy economically feasible, but I believe...
that many organizations purchase their blocks, drops and other compounded prescriptions from a licensed compounding pharmacy.

“We evaluated all of our options: buying from an outside pharmacy, partnering with a pharmacy and giving that pharmacy all of our business volume or doing it in-house,” Albertz says.

CEI was performing about 9,500 surgical cases per year in 2012 and had been considering its own pharmacy before the NECC incident. Albertz says he calculated that it costs $15 to $18 per case to acquire medications from an outside pharmacy.

CEI decided to contract with a compounding pharmacist to run the new operation. From there, CEI purchased the necessary equipment, set up the pharmacy and pursued licensure from their state pharmacy board. CEI was licensed and began compounding early in 2013. The institute now prepares its own bevacizumab (Avastin, Genentech), blocks, gels, steroids and vancomycin. (CEI still uses an outside pharmacy for mitomycin C, which Albertz says requires additional equipment and procedures to prepare. They’re investigating bringing that in house, too.)

“Every day, we evaluate our operating schedule 2 days in advance to determine what we need for each patient on each day, then we place an order with our pharmacy,” Albertz says. “We produce it, separate it for each location, label it for each individual patient. The next day, we bring it down to the clinic or to the ASC and place it in a secure refrigerator.”

What started as an effort to provide for its own doctors’ compounding needs has grown into a revenue stream for the institute, which now provides compounding services for 19 clients in nine states.

In the fall of 2013, CEI was accredited by the Pharmacy Compounding Accreditation Board (PCAB), becoming one of the few accredited compounding pharmacies in Ohio. The PCAB is the compounding industry’s quality assurance program. The voluntary program is separate from licensure by the Ohio Pharmacy Board. “Becoming PCAB-accredited validated our processes and set us apart from others in the compounding industry,” Albertz said.

CEI’s surgery center case volume rose to approximately 11,000 cases in 2014, but their pharmacy compounded about 50,000 injections last year, according to Albertz. The strong growth of CEI’s pharmacy business illustrates that most facilities either can’t or won’t handle

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compounding on their own.

Benze agrees. “Most organizations just aren’t in the position to perform their own compounding and their option is to purchase their compounded medications from an outside pharmacy,” she says. Benze notes that the compounding pharmacy industry is also adjusting to regulatory changes in the wake of the NECC incident. She offers the following tips for selecting a quality compounding pharmacy:

1. Verify that the pharmacy is licensed in both the state in which it’s located and, if different, the state(s) where your practice is located. Pharmacy laws differ among states. A medication compounded under the regulations in one state might not meet the requirements of another state. Your state pharmacy board can tell you the states with which it maintains reciprocal licensure agreements. Those reciprocal agreements demonstrate compatible standards between states.

2. Request evidence of accreditation by the Pharmacy Compounding Accreditation Board (PCAB) from a potential pharmacy. Participation in this voluntary accreditation process suggests the company is concerned about maintaining quality standards.

3. Ask to see proof of the pharmacy’s malpractice insurance coverage. Benze says it shouldn’t be difficult for a pharmacy to produce its licensure, accreditation and malpractice documents.

4. Obtain references. Ask for references from organizations that order similar medications to those your ASC would use.

5. Check for pharmacy infractions with the appropriate state pharmacy board. State boards maintain records of pharmacy infractions. The FDA also posts inspection results on the drug Guidance, Compliance & Regulatory Information section of the FDA site.5

6. Create a business contract with your supplying compounding pharmacy. A contract helps define the level of service expected, Benze says.

Emergency Cases

While ordering compound medications for a specific patient from a licensed pharmacy increases costs and management time for ASC staff, the lag time also raises clinical concerns about how to handle emergency cases. The requirement to order a compounded medication for a specific patient requires time to prepare and deliver it, potentially causing a dangerous delay in treatment.

Richard Mackool, MD, of the Mackool Eye Institute in Astoria, New York, offers the example of a patient who presents with extremely high and uncontrollable intraocular pressure (IOP), requiring an emergency trabeculectomy procedure and administration of mitomycin C (MMC).

“If the procedure is done that day without the use of MMC, it’s much less likely to be successful in lowering IOP,” Dr. Mackool says. “If it’s delayed in order to procure the MMC, the patient may suffer permanent damage to his or her vision as a result of the disease.”

Similar situations arise with intravitreal antibiotics for treating endophthalmitis cases, compounding fortified topical antibiotics for bacterial corneal ulcers, vascular endothelial growth factor (VEGF) inhibitors for macular degeneration and compounded combination dilating drops for pediatric patients.6

Under current regulations, ophthalmologists don’t have a clearly defined, compliant way to treat emergency cases. Albertz and CEI took this issue to the Ohio state pharmacy board in reference to bevacizumab injections. CEI asked what they should do if someone comes in on an emergent basis and needs the VEGF inhibitor injection. They asked whether, based on the specific-patient requirement, they were to deny a needed injection to a patient who may have driven a long distance to get to the clinic.

The pharmacy board allowed CEI to keep a small stock of compounded medications as an emergent care reserve, Albertz says. There’s no specific rule about keeping a reserve for emergency cases in the Ohio regulations so it’s not a complete solution, but Albertz believes it’s smart to take a proactive approach and ask your pharmacy board how to handle emergency situations.

“It gives you a resource and a bit of a safety net,” Albertz says, “but you have to police your expiration dates and police yourself to make sure you’re not taking advantage of the situation. Once you have that discussion with your pharmacy board, do what you said you would. They may drop in unannounced to see your inventory. You don’t want them finding that 25% of your syringes aren’t labeled for specific patients.”

Dr. Mackool believes current regulations must be changed to specifically allow an ASC or practice to keep an appropriate medication reserve on hand so ophthalmologists can promptly and appropriately treat emergent cases in compliance with the regulation. He says the Mackool Eye Institute obtains its compounded medications from an outside pharmacy for its planned procedures, but the specific-patient requirement actually puts some patients at risk instead of protecting them as intended. The Outpatient Ophthalmic
Surgery Society, American Academy of Ophthalmology and other societies are lobbying for regulation or legislation to specifically address compounding related to emergent care.

**Immediate-use Exception**

So-called immediate-use compounding is another option ophthalmologists can consider for some low-risk medications, according to Benze. However she cautions that the USP 797’s immediate-use exception has specific guidelines that require nurses or other appropriately licensed personnel to mix medications in a syringe, use specific labeling requirements and mandate that the preparation be used within 1 hour of preparation. The timing constraints of this approach would likely alter workflow in a facility and only provide a partial solution.

**Summary**

The tightening regulatory environment has driven most ophthalmic ASCs and practices to order their compounded medications from an outside pharmacy, increasing costs and adding to inventory management issues. Increased enforcement of the single-patient requirements has created legitimate concerns about emergency cases. Ophthalmic practices should carefully evaluate potential pharmacies, stay informed about any changes in their state pharmacy requirements, and consider seeking guidance regarding the unresolved issue of how to handle compounded medications in emergency situations.

**References**

Beyond the Data

Researchers report findings on largest study of ECP performed in conjunction with cataract surgery.

In the largest study on endoscopic cyclophotocoagulation (ECP) performed in conjunction with cataract surgery to date, researchers found that combined ECP and cataract surgery resulted in lower IOP and a greater reduction of the need for glaucoma medications than cataract surgery alone in patients with medically controlled open-angle glaucoma (OAG) and cataract. The study was conducted over a 3-year period. Here is an analysis of the clinical implications of this long-term data.

Clinical Findings

Patients with medically controlled OAG and visually significant cataracts were treated with ECP and cataract extraction or cataract extraction alone. The groups were matched in age and baseline IOP. Researchers then measured the change in IOP, number of glaucoma medications used, visual acuity and postoperative complications.

In the study group comprised of 80 patients, the number of glaucoma medications decreased from 1.5 ± 0.8 to 0.4 ± 0.7 at 1 year, 2 years and 3 years. Mean IOP decreased from 18.1 mm Hg ± 3.0 at baseline to 16.0 ± 2.8 mm Hg at 1 year, 16.0 ± 3.3 mm Hg at 2 years, and 15.4 ± 2.5 at 3 years. The control group of 80 eyes did not experience a significant decrease in IOP or medications at 1 year, 2 years nor 3 years. The visual acuity and rate of complications were similar in both groups.1

The findings of this study are like no other due to the matched control arm of patients who underwent cataract extraction alone, the large number of patients and the length of follow-up. The study shows that adding ECP to phacoemulsification is effective in decreasing IOP as well as the number of glaucoma medications. Cataract surgery alone resulted in medication reduction in a small number of patients within 6 months that was not sustained beyond 1 year. Also, both groups experienced an initial downward trend in IOP that peaked at the end of the first postoperative year. However, the eyes that underwent ECP and cataract surgery maintained lower IOP during the following 2 to 3 years, while the eyes that underwent cataract surgery alone regressed to a level that was higher than the initial IOP. Adding ECP did not increase the risk for serious complications compared with cataract surgery alone.

These findings confirm that ECP is a safe and effective adjunct to cataract surgery. The results are encouraging because they demonstrate that by addressing glaucoma and cataract simultaneously, we not only have the potential to lower IOP but also may be able to reduce the need for glaucoma medications, which reduces the costs, treatment burden and side effects for patients.

Clinical Relevance

As a surgeon who has been performing ECP since 1998, I feel the ideal patient for a combined ECP and cataract surgery procedure has visually significant cataract and medically controlled glaucoma. ECP combined with cataract surgery provides a third choice beyond the previously existing options, which were cataract surgery combined with a surgical trabeculectomy or cataract surgery alone. Surgical trabeculectomy, in these patients, is considered excessive because trabeculectomy warrants an...
extensive and involved postoperative course and an increased potential for complications in the early and late postoperative period. Alternatively, cataract surgery alone doesn’t help glaucoma in the long term. Therefore, a “cataract plus” procedure, which entails performing cataract surgery with modern phacoemulsification techniques using the E2 and E4 laser endoscopy systems (Endo Optiks, Inc.) to perform ECP, has been ideal.

In 1998, after analyzing the first 25 cases I performed with a phacoemulsification/ECP procedure with a follow-up of 6 months, I found that combining ECP with cataract surgery resulted in IOPs with an average of 2 to 3 points lower than the preoperative IOP as well as a significant reduction in medication in the range of approximately 50% to 60%. This approach is beneficial to the patient’s quality of life, because he doesn’t have to take as many medications or endure the side effects or expense of medications.

A Comparison
ECP is the first and most proven microinvasive glaucoma surgery (MIGS). Typically, MIGS procedures are performed with the same indications as someone who has cataract and glaucoma, and they’re performed through the phaco incision so there are no additional conjunctival or scleral incisions. The procedures are fairly simple and easy when performed as an add-on procedure to phacoemulsification, and they offer a benefit in terms of lowering IOP and reducing medications. However, after exploring other MIGS procedures, to include stent implantation (iStent, Glaukos) or trabeculotomy ab interno (Trabectome, NeoMedix), I found that performing those procedures at the end of cataract surgery involves rotating the patient’s head 45° degrees away from the surgeon, rotating the surgical microscope 45° degrees toward the surgeon to create an extreme tilt, placing a gonioprism lens on the cornea, visualizing and treating the trabecular meshwork directly, or implanting a stent in the Schlemm’s canal. Even though I’m an experienced surgeon, I found those steps difficult to perform while maintaining visibility and positioning the implants accurately. I prefer ECP because it’s simple and more predictable, with fewer complications and a short learning curve.

Long-Term Study Data
There is some confusion in regard to the effects of cataract surgery alone on IOP. Phacoemulsification alone can lower IOP in some patients, but that tends to be short lived as the reduction may last for 6 months to 1 year, which I call the “honeymoon” period. After that time period, the IOP tends to slowly increase, and by the end of 2 years, not only is the IOP back to baseline but the amount of medication required also returns to baseline. Conversely, patients who undergo ECP combined with phacoemulsification have a long-term decrease in IOP and a long-term reduction in the need for medications.

In 2009, Brooks Poley, MD, reported that patients who have a high IOP are more likely to experience an increased reduction in IOP when they undergo cataract surgery alone. However, it’s important to note that the patients Dr. Poley treated didn’t have glaucoma nor were they being treated for glaucoma, and patients with IOPs under 20 mmHg didn’t experience a pressure-lowering effect. Dr. Poley’s findings weren’t based on patients with concomitant cataract and glaucoma. Although his findings are relevant, some surgeons have misinterpreted the data to mean that cataract surgery alone will benefit their glaucoma patients in the long term. Our recent findings dispel any misinterpretations. They reveal that cataract and glaucoma, two of the most common conditions causing visual impairment in our patient population, can be treated effectively with ECP combined with cataract surgery, yielding long-term, positive outcomes.

References
In 2015, the Current Procedural Terminology (CPT) codes for aqueous shunts were revised so that there are now four codes for aqueous shunts — two with grafts and two without grafts. As noted in “CPT Changes: An Insider's View for 2015,” the insertion of an aqueous graft (prior CPT code 66180) and scleral reinforcement (67255) were reported together 73% of the time. It is now mandated that the two codes no longer should be coded together and, in fact, are bundled in the National Correct Coding Initiative. Medicare has very specific changes and new rules for coding and billing the new glaucoma codes.

2015 CPT Code Changes
Here are the changes in glaucoma coding for 2015. For a given year, CPT nomenclature indicates a new code for that year by placing a red bullet (•) before the code. Comments that are printed in green with text inserted between ▲ are added new material. The blue triangle symbol (▲) indicates the code description has been revised from the previous year.

NEW CPT CODES
Category I Codes
• 66179 Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft ▲66180 with graft ▶Do not report 66180 in conjunction with 67255 ▼ ▲66184 Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft ▲66185 with graft ▶Do not report 66185 in conjunction with 67255 ▼

DELETED CPT CODES
66165 Fistulization of sclera for glaucoma; iridencleisis or iridotasis

Category III Codes
The Category III codes are Emerging Technology Codes and are actually updated every 6 months. They can be accessed online at the AMA website (http://www.ama-assn.org). This is somewhat confusing due to the vagaries of the system. The implementation date occurs 6 months after the release date. The appearance of the code in the CPT book depends on the cycle. You may begin using the code on the implementation date even though it does not appear in that year’s CPT. On Jan.1, 2015 codes were released that you may begin using July 1, 2015.

The following changes for Category III glaucoma codes appear in CPT 2015.

The + sign always signifies that it is an add-on code and can only be used with a primary code and not by itself.
▲0191T Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion
+ ▲0376T each additional device insertion (List separately in addition to code for primary procedure)
▶ Use 0376T in conjunction with 0191T ▼ ▲0253T Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space

Microinvasive Glaucoma Surgery (MIGS)
MIGS is commonly used to refer to both Microinvasive or Minimally Invasive Glaucoma Surgery, but either way
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Efficiency
BECAUSE IT’S TIME FOR BETTER
the surgical procedures involve the use of less invasive and traumatic surgery coupled with utilization of smaller devices that work by channeling aqueous outflow to what may be considered as another anatomic site: Schlemm’s canal, suprachoroidal space or subconjunctival space.

Category III code 0191T, should be used for coding those devices, such as iStent (Glaukos Corp.), wherein the stent is inserted to bypass the trabecular meshwork and channel the aqueous from the anterior chamber into Schlemm’s canal. The only FDA approved stent at this time is iStent and the only approved usage is for the initial insertion when the surgery is performed for treating mild to moderate glaucoma in conjunction with cataract surgery.

When coding for a device that channels aqueous into the suprachoroidal space, use Category III code 0253T. At this time, there are no FDA approved devices that fit into this category.

When the aqueous is channeled into the subconjunctival space, the coding is problematic since at this time there is no Category III code and, in ASC coding, unlisted CPT codes (in this case 66999) cannot be used. The surgery is thus not covered for Medicare when performed in an ASC and the patient would be responsible for all aspects: physician’s, facility (including cost of the device) and anesthesia fees. Usually, these cases are referred to another type of facility.

The current FDA approval of iStent is for initial insertion of a single stent at a given session. The use of an iStent as an additional stent at the same session (new code 0376T) is not FDA approved. The ASC payment is packaged with that of 0191T. It has an N1 Payment Indicator (PI) and no extra payment is made to an ASC for packaged items. The January 2015 national ASC payment amount for procedure code 0191T is $1,711.02.

For physician coding it would be incumbent upon the physician to follow proper protocols regarding off-label use when inserting multiple iStents. This includes the following: an addendum to the iStent informed consent form if you use the one Ophthalmic Mutual Insurance Company (OMIC) provides, or any other one, regarding the use of multiple stents at the same session; a separate informed consent for using the second device as off label; and a written confirmation informing the patient of financial responsibilities for

**ASC CODING EXAMPLES**

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>CPT CODE(S)</th>
</tr>
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<tbody>
<tr>
<td>Surgery consists of placement of aqueous shunt (tube inserted) with Tutoplast (IOP Ophthalmics) graft.</td>
<td>CPT code 66180 (Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft).</td>
</tr>
<tr>
<td>Surgery on patient with neovascular glaucoma. Prior operation consisted of repair of retinal detachment (including use of gas) and placement of an aqueous shunt, but with the tube placed in the subconjunctival space underneath the Tutoplast graft. The tube was identified and freed from underlying sclera. The pars plana port was opened and the tube was placed in the pars plana.</td>
<td>CPT code 66184 (Revision of aqueous shut to extraocular equatorial plate reservoir; without graft).</td>
</tr>
<tr>
<td>Surgery on patient for cataracts and mild to moderate open angle glaucoma (phacoemulsification with insertion of intraocular lens + insertion of initial iStent).</td>
<td>CPT codes 0191T (Insertion of anterior segment aqueous drainage device, without extracocular reservoir, internal approach, into the trabecular meshwork, initial insertion) + 66984 (phacoemulsification cataract extraction with insertion of intraocular lens).</td>
</tr>
</tbody>
</table>
the procedure/device and having a signed Advanced Beneficiary Notice (ABN). It’s a good idea for the ASC to make sure all of the above are in order before scheduling multiple stent procedures.

“FOR PHYSICIAN CODING IT WOULD BE INCUMBENT UPON THE PHYSICIAN TO FOLLOW PROPER PROTOCOLS REGARDING OFF-LABEL USE WHEN INSERTING MULTIPLE iSTENTS.”

Medicare Coding Tips
• For both ASC and Physician Coding, CPT code 0191T should be coded first on the claim, before the cataract surgery code, since it is the highest paying code.
• The codes for aqueous shunt placement (CPT code 66179) + scleral reinforcement (CPT code 67255) + modifier 59 to break the NCCI bundles should not be used. Medicare would consider it improper coding for any procedures performed January 1, 2015 or after since it would be done with the intent of gaining unwarranted reimbursement.
• From the physician’s perspective, use any of the MIGS stents that are not FDA approved constitutes an off-label use, and the ASC should ascertain that the physician has completed all protocols mandated for such use. Seek help from your malpractice insurer or health care attorney if necessary.
• Always abide by your Medicare Administrative Contractor’s Local Coverage Determination (LCD) regarding guidelines and regulations for use of these codes.
• CPT code 0376T is an add-on code, which means it is used for multiple stents that are inserted at the same session. Add-on codes are always attached to a primary code and cannot be billed alone.

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WARNINGS AND PRECAUTIONS: Inform patients of possible contrast sensitivity reduction and increases in visual disturbances that may affect their ability to drive at night or in poor visibility conditions. The lenses are intended for placement in the capsular bag and should not be placed in the sulcus. Weigh the potential risk/benefit ratio for patients with conditions that could be exacerbated or may interfere with diagnosis or treatment. Secondary glaucoma has been reported occasionally in patients with controlled glaucoma who received lens implants. Multifocal IOL implants may be inadvisable in patients where central visual field reduction may not be tolerated, such as macular degeneration, retinal pigment epithelium changes, and glaucoma.

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