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BUSINESS MATTERS

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CONTROL WHAT YOU CAN



If you attended AAO in Orlando this year (and didn't sneak out to ride the new Guardians of the Galaxy coaster), you heard Paul Hahn, MD, PhD, provide a wonderful talk on the benefits of independent practice—a less popular practice models that's experiencing a resurgence as of late.

During his lecture, Dr. Hahn reviewed the annual ASRS Preferences and Trends (PAT) survey (this year totaling 991 respondents). The survey revealed that approximately 29% of practice owners have sold to private equity, and roughly 44% of respondents do not claim ownership in their practice (whether group or solo), leaving about 56% who still do.

The PAT survey also showed that only 9.6% of respondents run a solo private practice. Thus, while solo practice isn't quite a dying model, it's "a species at threat," Dr. Hahn noted in his talk.

If you round up that 9.6% to 10% of our work force, that's roughly 300 retina specialists across the entire country who captain their own ship. This group may be small, but they are mighty, and the appeal of solo practice is encouraging many clinicians to take the leap. Anecdotally, I overheard more than one retina fellow mention their decision to open their own practice right out of fellowship. Such go-getters!

So, what is the appeal? Control, Dr. Hahn explained. Above and beyond setting your own hours, choosing your own equipment, and handling employee benefits, you also oversee all the finances. You control your inventory, prior authorizations, medication float, cash flow, investments, accounts receivable…and the list goes on.

To help this endangered species of our field, this issue focuses on building a private practice from the ground up. Peter Karth, MD, MBA, FASRS, FACS, offers a helping hand for those ready to experience "the most rewarding professional endeavor you'll undertake." In his article, "Beyond the Checklist: Insights for Starting a Retina Practice," Dr. Karth outlines five steps you must take to build a strong practice, starting with strategic initial investments and the right way to handle your high-cost injectable medications. It's a must-read for anyone toying with the idea of striking out on their own (retina fellows, take notes!).

If you aren't looking for solo practice pearls, this issue also includes tips to help you improve your website while maintaining patient privacy, how to code complex cases (using CPT code 67113), ways to reduce your taxes and shield your wealth, and how to ensure a patient's privacy when they are using your practice's website.

Regardless of your practice model, this issue is designed to help you control what you can and find ways to improve patient care and your business, whether you own it or not. ■

ALAN RUBY, MD
SECTION EDITOR

TABLE OF CONTENTS

4 **Four Tactics to Reduce Taxes and Shield Wealth From Liability**
By David B. Mandell, JD, MBA, and Carole Foos, CPA

6 **Beyond the Checklist: Insights For Starting a Retina Practice**
By Peter Karth, MD, MBA, FASRS, FACS

9 **Using CPT Code 67113 With Confidence**
By Joy Woodke, COE, OCS, OCSR

10 **Negotiating Contracts in Retina**
Editorially independent content supported by Genentech and Ocular Therapeutix

12 **Provider Websites and Patient Privacy**
By Nancy L. Perkins, JD, MPP

FOUR TACTICS TO REDUCE TAXES AND SHIELD WEALTH FROM LIABILITY



Sometimes, you can have the best of both worlds with these financial tips and tricks.

BY DAVID MANDELL, JD, MBA, AND CAROLE FOOS, CPA

Many physicians, including retina specialists, would rank tax reduction at the top of their financial planning goals—with asset protection not far behind. Tactics that can result in both benefits would naturally be of high interest. Here, we briefly describe four common options you can employ to reduce your taxes while also protecting your assets.

LEVERAGE THE PRIMARY RESIDENCE

If the adage is "a man's home is his castle," that castle may enjoy both asset protection and tax benefits. Regarding asset protection, nearly every state protects some, or all, of a home's equity from lawsuits and creditor claims. State laws do vary significantly here, ranging from no protection in New Jersey to protection of an unlimited amount of home equity in states such as Florida and Texas. Be sure to check with an asset protection expert to understand how your state's homestead law protects your home equity.

The tax benefits of home ownership are consistent in all states and include the ability to write off mortgage interest (with limitations), as well as a $500,000 capital gain exclusion for a married couple on the sale of a home ($250,000 for single filers). In addition, local property taxes on a primary home can be deductible against your federal income tax, although that deduction has become more limited in recent years.

FOCUS ON RETIREMENT PLANS

From a tax point of view, qualified retirement plans (QRPs) and IRAs all provide a current tax deduction against a retina specialist's income, so they are extremely attractive for tax planning. In fact, these tax deductions can range anywhere from approximately $20,000 for 401(k)s to $200,000 or more for certain types of defined benefit plans.

In terms of asset protection, these plans often have the highest level of creditor protection under state law. Of course, there is variation between all 50 states, and some states provide the highest level of protection only for a limited dollar amount. Nonetheless, for most states, this protection is at an unlimited dollar level. Check with an asset protection expert on the protections in your state.

IRAs are technically not QRPs, although they act like them in many financial and tax respects. A simplified employee pension IRA can provide the same tax deduction level as certain QRPs, while a Roth IRA has a different tax treatment but is also beneficial. A Roth acts more like a non-qualified plan in that there is no deduction for contributions, but the assets grow tax-free and come out tax-free.

DON'T FORGET ABOUT NON-QUALIFIED PLANS

Physicians use non-qualified plans less often than QRPs, which is unfortunate. When it comes to tax protection, non-qualified plans work similar to a Roth IRA: There is no deduction for the contribution, but the funds grow tax-free

MANY DOCTORS, WHEN ASKED, WOULD LIKE TO PUT MORE INTO A ROTH IRA-TYPE VEHICLE YET FAIL TO CONSIDER A NON-QUALIFIED PLAN—A TOOL THAT COULD ACHIEVE THIS OBJECTIVE.

in the plan and can come out tax-free in retirement. In fact, many doctors, when asked, would like to put more into a Roth IRA-type vehicle yet fail to consider a non-qualified plan—a tool that could achieve this objective.

Non-qualified plans often fund into a permanent life insurance policy. Thus, the level of asset protection is dictated by state rules regarding permanent (also called cash value) life insurance.

The other benefit of a non-qualified plan is that it is quite flexible. Unlike a QRP, the non-qualified plan does not need to be offered to any employees. It can be completely discriminatory. In this way, a practice can sponsor a non-qualified plan just for the physicians, just for partners, or just for a few doctors who want to participate.

CONSIDER PERMANENT LIFE INSURANCE

Permanent life insurance is shielded to some degree from creditors under state law. Once again, these exemptions vary significantly between the 50 states.

From a tax point of view, the benefits are consistent throughout the United States because they emanate from the federal tax code. These include the ability for the cash value of permanent policies to grow tax-free and, if managed properly, be accessed tax-free. Death benefits paid to beneficiaries are also generally income tax-free under Section 101 of the code.

Further, the IRS allows for the tax-free exchange of these types of policies, using a like-kind exchange. You may have read about such tax-free exchanges when it comes to real estate, but life insurance is another asset class favored with this tax benefit. Using this technique can be very beneficial because you could move cash value from one policy to another over time with no taxation. This might be attractive if costs come down, new policies are more attractive, or new features of competing policies are more aligned with your planning.

THINK OUTSIDE THE BOX

If tax reduction and asset protection are important planning objectives for you, be sure to examine each of these four tactics with an experienced advisor and implement the one(s) that are best aligned with your long-term financial goals. ■

SPECIAL OFFER: Mr. Mandell and OJM Group partners are pleased to announce the publication of their newest book, Wealth Strategies for Today's Physician: A Multi-Media Playbook. *The* Playbook's *innovative format features more than 90 links to videos and podcast episodes to enhance important financial topics for physicians. To receive a free print copy or ebook download, text RETINA to 844-418-1212, or visit www.ojmbookstore.com and enter promotional code RETINA at checkout.*

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BEYOND THE CHECKLIST

INSIGHTS FOR STARTING A RETINA PRACTICE



Here are five critical pearls I wish I had known when I opened my own retina practice.

BY PETER KARTH, MD, MBA, FASRS, FACS

Starting your own retina practice can be daunting, but it's also the most rewarding professional endeavor you'll undertake. Numerous resources and checklists exist to help you through the process, including contracting and credentialing, office space, equipment purchases, payroll, hiring, marketing, suppliers, and billing. Navigating these mechanics of practice building is relatively straightforward—you simply execute each task or find a vendor to handle it.

What's less clear and rarely discussed are several specific, critically important aspects of your new practice, and these make all the difference between success and struggle. Here are the most crucial considerations for effectively starting and operating your new retina clinic.

MASTER YOUR HIGH-COST DRUG MANAGEMENT

Using high-cost injectable medications is inherently challenging but essential for the modern retina practice. Changes in their use can devastate your finances and cash flow unless you manage them properly, while reimbursement failures can cripple your practice and destroy your financial stability. If you're using more than a few high-cost medications each month, you need comprehensive systems to keep track of them, spanning from ordering to collections and even paying invoices. The dollars associated with medications will quickly dwarf all other financial aspects and may distort your entire financial picture without proper management. I recommend being all in or all out.

Inventory Management

Implement an inventory management software system from day 1. These systems typically have no out-of-pocket costs and are invaluable for tracking every dollar and dose. Daily reports that highlight missing or unbilled doses are essential, and they will save you significant headaches and money by preventing costly oversights that multiply rapidly if not addressed in a timely fashion.

Prior Authorization and Step Therapy Mastery

Understanding the ins and outs of prior authorizations and step therapy on the individual patient level must become a core competency with established protocols, workflows, and clear accountability. As the provider, you need 100% confidence that prior authorization and patient assistance have been secured before administering an injection. You must understand the applicable step therapy progression for each patient at every visit so that you can order and obtain prior authorization for the correct medication. This knowledge must be patient-specific and available in the clinic during every encounter—there's no room for doubt or mistakes. While you can handle this personally during your first weeks or months as a solo practitioner, you'll need to delegate this complex, time-consuming process to a dedicated staff member early, before the clinic is too busy to allow you the time to train them properly.

Medication Float Management Strategy

Medication float is best defined as: expected collections from medication + value of medication inventory – total medication invoices. This encompasses your entire medication financial cycle. Your default target should be zero, except in special circumstances. Bring this equation to zero weekly by paying invoices in amounts needed to balance it. Whatever remains in your bank account after balancing represents your true cash-basis profit, which can be safely reinvested or distributed.

Avoid taking distributions until you've zeroed this equation through invoice payments, unless you're knowingly drawing against future profits. Without this discipline, your financial statements will show false profits or losses, rendering them essentially useless for decision-making, and you will lose all sense of financial performance.

STRATEGIC INITIAL INVESTMENT AND FINANCING

Investment requirements depend on numerous factors: office size and location, equipment type and quantity, and personal practice style preferences. While it can be difficult to provide specific advice given these variables, you can minimize startup costs with creative thinking.

To determine your required initial investment, calculate your first 90 to 180 days of operating expenses, including all cash outlays. The timeline variance depends on how quickly you expect patient visits and collections to grow. Both are difficult to control and involve educated guessing, but trust yourself; whether you ramp up quickly or slowly, hard work will lead to success.

Once you determine your capital requirements, consider multiple funding sources such as personal savings, including cash and investments from non-tax-advantaged accounts. Don't hesitate to invest in yourself; your retina practice will likely become the best-performing asset you'll ever invest in.

Consider family and friend investments. While this may feel uncomfortable, retina practices differ fundamentally from typical speculative startups. Standard startups have high failure rates; retina practices have very high success probabilities. Don't hesitate to use family funds to start your practice. Banks typically offer physician loans or lines of credit, although you may need collateral and will pay interest. Don't let startup capital requirements prevent you from moving forward because they are a solvable challenge.

UNDERSTAND INITIAL CASH FLOW PATTERNS

You'll begin with startup capital in your business account, regardless of source. Collections flow in while expenses flow out. After zeroing your medication float, you'll see the weekly bank balance begin to increase at some point—your first

AT A GLANCE

- When starting a retina practice, you must have comprehensive systems to keep track of the high-cost drugs, from purchase to payment.
- To determine your required initial investment, calculate your first 90 to 180 days of operating expenses, including all cash outlays.
- A reasonable working capital target is 1 to 2 months of non-medication operating expenses after zeroing medication float.

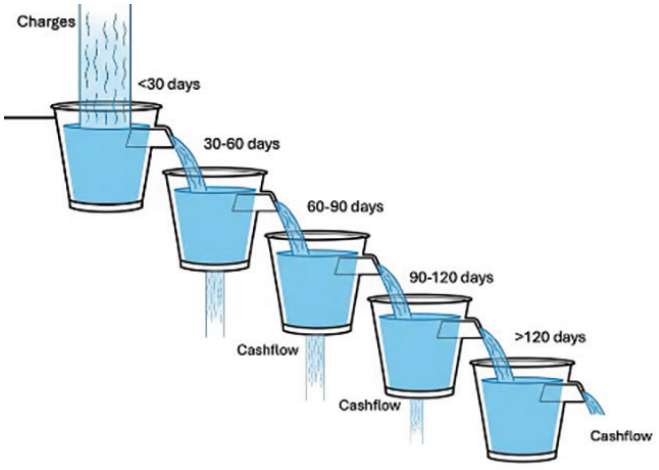


Figure. Accounts receivable can be conceptualized as buckets, and you will only realize cash flow after each bucket has been filled.

sign of sustainable profitability. Monthly draws or paychecks will slow this timeline, naturally. Remember that personal benefits (ie, health insurance), 401(k) contributions, and paychecks represent cash withdrawals from the business. These reduce business profitability but increase the personal benefits from your work.

When you see excess cash accumulating, consider your options carefully. While reinvesting in equipment or services may (or may not) accelerate growth, consider prioritizing repaying initial startup capital and building working capital reserves. Repay startup capital first, regardless of source. If your startup capital was $100,000, your business needs $100,000 in profit to repay it.

ESTABLISHING APPROPRIATE WORKING CAPITAL

Working capital—ie, money in your business checking account for daily operating expenses considering collection fluctuations—lacks clear industry guidelines. Solo practitioners can maintain lower reserves by ensuring personal emergency fund access. A reasonable working capital target is 1 to 2 months of non-medication operating expenses after zeroing medication float.

Remember, you are building working capital from company profits, and company profits are taxed, even if not withdrawn. Working capital is the post-tax dollars that you leave in your company; it is earned and taxed as profit, but not paid out in wages or distributions. To obtain $100,000 from operations to be held for working capital, you'll need approximately $200,000 in pre-tax profit to cover roughly $100,000 in taxes. That can feel like a lot of work and effort, with nothing ending up in your personal bank account.

MANAGE ACCOUNTS RECEIVABLE DYNAMICS

Like every medical practice, you'll maintain substantial accounts receivable due to the lag between service delivery and payment collection. In my experience, average collection lag is 60 days, although this varies regionally.

Think of accounts receivable in aging buckets: < 30, 30 to 60, 60 to 90, 90 to 120, and > 120 days from the service date (Figure). Standard practices will always have some accounts receivable in each bucket, typically as a fixed percentage of collections, distributed across timeframes.

Critically, you must "fill" each bucket with charges before realizing true cash flow. It's oversimplified to think, "I know there will be a lag until cash starts coming in." Your charges must fill each bucket as a percentage of collections before full cash flow materializes for that patient visit level.

Simultaneously, rapid practice growth means expanding the size of each bucket as a percentage of collections. Each month, some growth in your charges must fill the now-larger buckets and will rest in longer-dated categories. Early in the setting of high growth, this creates constant cash flow drag, making it feel like you are seeing more patients without proportional cash flow increases.

Adding high-cost injectables compounds this effect through dramatic charge increases; it also compresses your overall margins massively, while increasing your total revenue exponentially. Recognize this pattern as normal and expected—your persistence will be rewarded as the practice matures.

PREPARATION AND PERSISTENCE ARE KEY

Once you have your monitoring systems set up, it only takes a few minutes each week to keep everything on track. It is critical that you, personally, have a true pulse on your business, just like you need to have a pulse on your patients. Setting healthy management habits early will help you avoid common pitfalls of starting a practice. They will also ensure you thrive as a business owner and your patients are receiving the best possible care. ■

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Vitreous Dysfunction: A Focus on Patient Selection

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The importance of active listening and proper classification and treatment when managing patients with visually significant vitreous opacities.

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USING CPT CODE 67113 WITH CONFIDENCE



Coding for a complex retina detachment doesn't have to be complicated when managed properly.

BY JOY WOODKE, COE, OCS, OCSR

CPT code 67113—repair of complex retinal detachment (RD)—is one of the most nuanced codes in vitreoretinal surgery. Because the code includes multiple procedures and has a designation as a CGS audit target, accurate coding and documentation are more critical than ever.

UNDERSTANDING THE CODE

The indications for CPT code 67113 are: RD and proliferative vitreoretinopathy (PVR), diabetic tractional RD, retinopathy of prematurity, or retinal tears greater than 90°.

The procedure must include both pars plana vitrectomy and membrane peeling; additional procedures may include the following:

- Air, gas, or silicone oil tamponade
- Cryotherapy
- Endolaser photocoagulation
- Drainage of subretinal fluid
- Scleral buckling
- Removal of lens

This bundled code reflects the intensity and complexity of the procedure. It should only be reported when specific diagnoses and the required procedures are medically necessary and performed during the same operative session to repair an RD.

CGS AUDIT

CGS, a Medicare administrative contractor, has flagged CPT code 67113 as a targeted probe and educate (TPE) audit focus for ophthalmology services.[1] This means practices must be vigilant in justifying medical necessity, ensuring complete documentation, and avoiding overuse or misapplication.

CGS has a fact sheet that provides insight into the audit expectations, including establishing medical necessity based on RD type, proving a pars plana vitrectomy and membrane peeling are required, using the appropriate modifier(s), and completing compliant signature requirements.[2]

What to Expect From a TPE

TPE audits can be either a pre- or post-payment audit. If you receive an audit notice, or an additional documentation request, you must respond within 45 days or you will fail the round. Each round examines 20 to 40 claims. After each round, a letter with the results is mailed and may require a review, called a *discussion and education*. If you fail the first round, you will face a second review. If a physician fails the third round, further action will be taken, including referral to a recovery auditor contractor, extrapolation, or other action.[3] Common claim errors include the following:

- The certifying physician's signature was not included.
- Encounter notes didn't support all elements of eligibility.
- Documentation did not meet medical necessity.
- Initial certifications or recertifications were missing or incomplete.

Bundled Procedures

Due to the complexity of the descriptor, many retina procedures are bundled with CPT code 67113 and should not be unbundled with modifier -59 when performed during the same session and on the same eye. A few examples of these bundles include the following:

- 67036-67043, family of vitrectomy codes
- 66850-66852, lens removal

(Continued on page 14)

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NEGOTIATING CONTRACTS IN RETINA

Empowered negotiation begins with understanding personal priorities, knowing your worth, and seeking the right professional advice.

Back by popular demand, YoungMD Connect hosted another interactive, virtual installation designed for residents and fellows on how to negotiate contracts in the retina field. Featuring Laxmi Devisetty, MD; Geeta Lalwani, MD; and Alan Ruby, MD, this workshop aimed to provide advice on understanding contract terms, negotiating consulting contracts with industry, and involvement of personal attorneys.

CONTRACT TERMS AND LIFESTYLE FACTORS

To begin the workshop, all expert panelists agreed one of the most important things to consider before negotiating a contract is determining what you value the most—location, family support, autonomy, growth potential, etc.

Dr. Devisetty opened the discussion by posing key contract topics for young doctors to consider prior to entering negotiation. First, she spoke on restrictive covenants and practice geography. For example, it's important to specifically negotiate non-compete terms such as potential geographic boundaries, clause duration, and any specific practice site exclusions. She also noted that many retina practices today require rotations across locations. Key questions to ask include: How far are the sites from one another? How frequently is travel required? Long commutes can impact quality of life, so gaining answers to these questions should factor into negotiation. Another important requirement is understanding the parameters around parental leave. Dr. Devisetty recommended to ensure maternity/paternity leave is explicitly stated in the contract, as this is a significant lifestyle factor for early-career physicians who are starting families.

She also highlighted sign-on bonuses, which she noted have become increasingly common post-fellowship. When discussing these bonuses, she said it's important to confirm any repayment triggers and bonus timeline should you leave the program early. Sign-on bonuses are particularly helpful for debt relief among early-career physicians.

Dr. Devisetty concluded her session by discussing on-call structure. She advised that young doctors clarify their call type (retina-only, general care, trauma, etc.) in their contracts. For example, confirm on-call frequency, call locations, hospital requirements, and whether compensation will be received from being on-call. Various hospital-implemented obligations can affect lifestyle needs or wants, though some are negotiable, so it's important to confirm what these are when reviewing the contract, Dr. Devisetty said.

CONSULTING WITH INDUSTRY

Next, Dr. Lalwani spoke on best practices for how to negotiate contracts within industry positions. Before committing to work in an industry setting, Dr. Lalwani advised attendees to confirm whether certain academia roles may restrict or limit industry work (1-year term limits, COI reporting, etc.). Furthermore, it's important to clarify whether certain private practices/private equity groups may require employees to share a portion of their external compensation.

In terms of when to begin initiating contact with industries, Dr. Lalwani suggested the earlier the better. Identifying companies/products of interest in fellowship or residency and reaching out proactively at meetings such as ASRS and AAO is important to place yourself on the radar. Don't underestimate your expertise; rather, offer clinical perspectives that companies value. This is also true when agreeing to participate in industry ad boards. However, to do this, it's vital to do your homework. Research the company and available or up-and-coming products, and ask thought-provoking questions. According to Dr. Lalwani, this is how to get your foot in the door to consult in an industry setting.

Another tip Dr. Lalwani provided attendees was to keep an updated CV on hand. This includes listing all up-to-date publications, leadership/society roles, and any prior work experience. Dr. Lalwani explained that often, companies use third-party evaluators to set fair-market value for consulting fees. In tandem, it's essential to understand the scope of work and what amount of preparation is expected. Dr. Lalwani advised:

- To clarify deliverables (pre-work, case studies, presentations, etc.).
- To always prepare—know relevant trial data, strengths/weaknesses, competitors, etc.
- That preparation distinguishes strong consultants and builds credibility.

When negotiating compensation in industry consultation roles, Dr. Lalwani shared that fees are usually flat or hourly, and travel is typically covered. However, her main point was

to maintain a mutual-beneficial mindset. Ultimately, she said, this is not all about receiving money. This is about building relationships and working together to help each side succeed in providing patient-centric care.

WORKING WITH AN ATTORNEY AND NEGOTIATION STRATEGY

To conclude the workshop, Dr. Ruby discussed the advantages of working with an attorney when in contract negotiations. While understanding the expense of hiring legal counsel, Dr. Ruby said he believes this is a critical investment. Working with an attorney can help clarify many aspects of a contract, including prevention of mistakes in restrictive covenant or sale-of-practice clauses.

Dr. Ruby explained the two most common approaches to working with an attorney. First, there is the attorney-led negotiation process, in which counsel directly interfaces with the practice, which is costlier but hands-off. Second, there is the attorney as reviewer process, in which the attorney marks up any contractual issues, but you negotiate with the practice yourself. For those concerned about cost, Dr. Ruby recommended the latter approach, as it is more financially efficient.

In terms of prioritization and strategy while negotiating, Dr. Ruby said to rank issues by importance, distinguishing the "must-haves" from the "nice-to-haves." He also stressed to attendees to ask for what you need without fear of sounding greedy. In his experience, Dr. Ruby said that practices respect self-advocacy when done professionally and with respect. During this process, it is also important to recognize what is and isn't negotiable. For example, many clauses are standard across group members and are hard to change. Working with an attorney can help streamline this process and determine when to implement addenda to personalize terms instead of editing the base contract. This includes relocation allowance, PTO for research/industry work, etc.

One of the final pearls Dr. Ruby shared was on non-compete clauses. While they are difficult to alter, it is possible to negotiate a delayed onset of 30-60 days out of fairness. For example, this protects being bound if a practice fails immediately after joining. Dr. Ruby concluded by echoing the importance of engaging legal counsel early and asking confidently and professionally for what you need.

TAKE HOME POINTS

This workshop emphasized that successful contract negotiations in retina begin with self-awareness and preparation, not paperwork.

The panelists emphasized that young physicians should first clarify what truly matters—location, family priorities, work-life balance, and professional goals—since these personal factors shape every other negotiation point. To conclude the workshop, the panelists echoed that empowered negotiation is about clarity, professionalism, and foresight. Knowing your priorities, understanding contract terms, and advocating for yourself—supported by the right legal and professional guidance—are the foundation for a strong start in retina practice. ■

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PRACTICE MANAGEMENT

PROVIDER WEBSITES AND PATIENT PRIVACY



Understanding the legal risks of tracking technologies.

BY NANCY L. PERKINS, JD, MPP

Most ophthalmologists maintain websites to promote their practices and facilitate patient onboarding, including the submission of new patient registration forms, insurance details, and medical histories. These websites often employ tracking technologies such as cookies, pixels, and tags, which collect data about a visitor's browser or device. This information allows the website to customize its responses during future visits and optimize the user experience. Some tracking technologies are supplied by third-party vendors, such as Google and Meta, which may use the collected data for purposes beyond website functionality, including targeted advertising. This could compromise patient privacy and raise legal concerns.

THE OFFICE FOR CIVIL RIGHTS' BULLETIN ON ONLINE TRACKING TECHNOLOGIES

In late 2023, the Office for Civil Rights (OCR) at the US Department of Health and Human Services—responsible for enforcing HIPAA's privacy, security, and breach notification regulations—issued a Bulletin highlighting the risks that online tracking technologies may pose to HIPAA-covered entities, such as health care providers and health insurance plans. The OCR Bulletin states that information collected through tracking technologies on covered entity websites, mobile applications, and patient portals may include personally identifiable health information, which qualifies as protected health information (PHI) under HIPAA if created or received by a HIPAA-covered entity or its business associate. The Bulletin also warns that using or sharing such information without the site visitor's consent may constitute unauthorized uses or disclosures of PHI.

DEFINING PHI IN THE DIGITAL SPACE

As noted in the Bulletin, the term *PHI* refers to individually identifiable information created or received by a HIPAA-covered entity that "relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual."[1]

Tracking technologies typically collect information about the device an individual uses to connect to a website, such as a device ID or an Internet Protocol (IP) address. In its Bulletin, the OCR asserted that this identifiable information, when combined with information about the individual's visit to certain covered entity websites, constitutes PHI under HIPAA because it indicates that the individual has requested, received, or will receive health care services or benefits from the covered entity operating the website.

For example, the OCR considers the history of an individual's browsing on a health care provider's website—such as visiting an ophthalmology practice's website to learn about cataract surgery or gather information on refractive surgery providers—to be PHI. Such information demonstrates that the individual has requested, received, or will receive health care services from that practice. The Bulletin warns that, if this information is shared without the individual's authorization, the covered entity may be liable for violating HIPAA's general prohibition on disclosing PHI without proper authorization.

CONTROVERSY OVER THE OCR'S BULLETIN

Joint Communication From the OCR and Federal Trade Commission (FTC)

Six months after issuing the Bulletin, the OCR, together with the FTC, sent a joint letter to approximately 130 hospitals, telehealth providers, health app developers, and other health care industry entities. The letter warned of the "serious privacy and security risks" associated with collecting information through online tracking technologies integrated into their websites and mobile applications.[2]

Lawsuit Challenging the Bulletin

In response, in November 2023, the American Hospital Association, the Texas Hospital Association, Texas Health Resources, and the United Regional Health Care System

OPHTHALMOLOGISTS SHOULD BE AWARE THAT, CITING CONCERNS ABOUT TRANSPARENCY AND PRIVACY, THE FTC AND PRIVATE PARTIES HAVE CHALLENGED THE USE OF CERTAIN TRACKING TECHNOLOGIES ON HEALTH-RELATED WEBSITES.

filed a lawsuit against the OCR in the US District Court for the Northern District of Texas. The lawsuit challenged the OCR's authority to issue the Bulletin and enforce the HIPAA Privacy Rule based on the Bulletin. The plaintiffs argued that the OCR erred in declaring that information collected via tracking technologies on HIPAA-regulated entities' unauthenticated public web pages (UPWs)—web pages that do not require visitor verification or login credentials—constitutes PHI.

For example, the plaintiffs contended that, even if an IP address of a visitor to a health-related UPW could be reliably associated with a specific individual, the combination of the IP address and the web page visit could not reasonably be assumed to reflect information about the individual's health, health care, or payment for health care. The plaintiffs noted that visits to UPWs might occur for reasons unrelated to personal health, such as academic or journalistic research, general curiosity about health-related topics in the news, or even accidental clicks on links. They asserted that the OCR's categorical characterization of information collected through certain tracking technologies as PHI lacks sufficient factual and legal basis.

The OCR's Revised Bulletin

Following an initial briefing, both parties filed motions for summary judgment. Shortly before its summary judgment brief was due, the OCR issued a revised Bulletin suggesting that user information collected on UPWs could be considered PHI if the individual's reason for visiting the web page was related to personal health care. The OCR posted the revised Bulletin with a disclaimer stating, "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way." Consistent with this disclaimer, the OCR argued that the Bulletin could not be challenged in court because it was not a "final agency action" subject to judicial review.

Judicial Response

The judge presiding over the case disagreed with the OCR's interpretation of its revised Bulletin.[3] The judge determined that the revised Bulletin provides guidance about mandatory legal obligations and therefore imposes substantive legal obligations. As such, the Bulletin qualifies as a "final agency action" and is subject to judicial review.

On the substantive content of the Bulletin, the judge ruled that the OCR exceeded its authority under HIPAA by stating that information collected through tracking technologies on HIPAA-regulated entities' UPWs constitutes PHI. The judge reasoned that, although an IP address can be considered identifiable information, there is no justification for concluding that health-related browsing information from a UPW linked to an IP address qualifies as health information about the individual associated with that IP address. The judge therefore found that the combination of an individual's IP address and their visit to a HIPAA-covered entity's UPW cannot automatically be classified as PHI under HIPAA.

The judge also rejected the OCR's argument that user information collected on UPWs constitutes PHI if the individual's purpose for visiting the website relates to their own health care. The judge found that such an approach would make the determination of whether information is PHI based on a subjective assessment of the "purpose and intent" of the website visitor. The judge concluded that, because HIPAA-regulated entities have no practical means of discerning the purpose or intent behind a visitor's use of an unauthenticated website or whether it pertains to the individual's health care, the OCR's focus on visitor intent lacks legal justification.

Outcome and Current Status

The judge vacated only the portion of OCR's Bulletin addressing the use of tracking technologies on UPWs. The OCR subsequently filed a notice of appeal to the US Court of Appeals for the Fifth Circuit to challenge the district court's order. However, 10 days later, the agency voluntarily withdrew the appeal. As of this writing, the OCR has not removed the Bulletin from its website. Instead, the OCR references the court order and states that the US Department of Health and Human Services "is evaluating its next steps in light of that order."[1]

CONSIDERATIONS FOR OPHTHALMOLOGY PRACTICES

Third-Party Tools and Data Disclosure

The OCR Bulletin remains in effect as it pertains to the use and disclosure of information collected through tracking technologies on authenticated parts of a website, mobile app, or portal. Accordingly, ophthalmology practices with websites, mobile applications, or patient portals should carefully evaluate the types of tracking technologies implemented on these platforms. The review should specifically consider whether PHI is being used or disclosed via tracking technologies, including tools provided by third parties such as advertising or social media companies, in ways that may require patient authorization.

Patient Authorization and Privacy Protections

Ophthalmologists should be aware that, citing concerns about transparency and privacy, the FTC and private parties have challenged the use of certain tracking technologies on health-related websites. The FTC has settled claims in cases involving companies such as BetterHelp,[4] Monument,[5] Cerebral,[6] and GoodRx.[7] Recently, GoodRx also agreed to settle similar claims brought in a consolidated class action in the US District Court for the Northern District of California.[8]

MITIGATING RISKS IN A CHANGING LANDSCAPE

Although the change in federal administration may reduce the likelihood of federal enforcement actions, private litigants and some state authorities are likely to continue advocating for stronger protections of individual privacy. Vigilance in safeguarding the privacy and security of patient information, whether collected online or offline, therefore remains essential. ■

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4. Federal Trade Commission. FTC gives final approval to order banning BetterHelp from sharing sensitive health data for advertising, requiring it to pay $7.8 million. July 14, 2023. Accessed January 23, 2025. www.ftc.gov/news-events/news/press-releases/2023/07/ftc-gives-final-approval-order-banning-betterhelp-sharing-sensitive-health-data-advertising
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CODING ADVISOR

(Continued from page 9)

- 66982-66984, cataract removal with IOL implantation
- 67028, intravitreal injection

CODING EXAMPLES

Diabetic Tractional RD

A patient with a diabetic tractional RD undergoes vitrectomy with membrane peeling, endolaser, and gas tamponade.

- Correct code: 67113
- Modifier: -RT or -LT as appropriate
- Documentation tip: Clearly indicate the extent of the tractional RD and the procedures performed, and include operative details such as membrane peel and tamponade agent used.

Recurrent RD Post-Vitrectomy

A patient previously treated with CPT code 67108 returns with a recurrent RD and extensive PVR. The surgeon performs vitrectomy, scleral buckle, membrane peel, and silicone oil injection.

- Current code: 67113
- Modifier: -58 (staged or related procedure during postoperative period)
- Documentation tip: Reference the prior surgery, explain the progression to a more complex repair, and include the rationale for each added procedure.

DOCUMENTATION CHECKLIST ESSENTIALS

To support CPT code 67113, your operative report should include the following:

- Diagnosis: Specify the complexity.
- Procedure details: Describe each component.
- Medical necessity: Explain why each step was required.
- Laterality and modifiers: Use -RT or -LT or modifiers -58, -78, or -79 when applicable.
- Postoperative plan: Include the follow-up strategy and any staged procedures.

SURVIVE THE AUDIT

With CPT code 67113 under scrutiny, coding accuracy is not just about reimbursement—it's about audit resilience and clinical integrity. By aligning documentation with payer expectations and surgical complexity, practices can confidently navigate this challenging code. ■

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- Financial disclosure: None

BRIEF SUMMARY OF PRESCRIBING INFORMATION
This Brief Summary does not include all the information needed to use XIPERE® safely and effectively. See full Prescribing Information for XIPERE®.

XIPERE® (triamcinolone acetonide injectable suspension), for suprachoroidal use

Initial U.S. Approval: 1957

INDICATIONS AND USAGE

XIPERE® (triamcinolone acetonide injectable suspension) 40 mg/mL is indicated for the treatment of macular edema associated with uveitis.

CONTRAINDICATIONS

4.1 Ocular or Periocular Infections XIPERE® is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

4.2 Hypersensitivity XIPERE® is contraindicated in patients with known hypersensitivity to triamcinolone acetonide or any other components of this product.

WARNINGS AND PRECAUTIONS

5.1 Potential Corticosteroid-Related Effects Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. Corticosteroids should be used cautiously in patients with a history of ocular herpes simplex. Corticosteroids should not be used in patients with active ocular herpes simplex.

5.2 Alterations in Endocrine Function Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use. Corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Drug induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

ADVERSE REACTIONS

6.1 Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. XIPERE® was studied in a multicenter, randomized, sham-controlled, double-masked study in patients with macular edema associated with uveitis. Table 1 summarizes data available from the clinical trial for XIPERE® treated patients and control patients. The most common ocular (study eye) adverse reactions occurring in ≥ 2% of patients and nonocular adverse reactions occurring in ≥ 5% of patients are shown in Table 1.

Adverse Reaction	XIPERE® (N = 96) n (%)	Control (N = 64) n (%)
Ocular		
Increased intraocular pressure, non-acute [a,b]	13 (14%)	9 (14%)
Eye pain, non-acute [b]	11 (12%)	0
Cataract [c]	7 (7%)	4 (6%)
Increased intraocular pressure, acute [a,d]	6 (6%)	0
Vitreous detachment	5 (5%)	1 (2%)
Injection site pain	4 (4%)	2 (3%)
Conjunctival haemorrhage	4 (4%)	2 (3%)
Visual acuity reduced	4 (4%)	1 (2%)
Dry eye	3 (3%)	1 (2%)
Eye pain, acute [d]	3 (3%)	0
Photophobia	3 (3%)	0
Vitreous floaters	3 (3%)	0
Uveitis	2 (2%)	7 (11%)
Conjunctival hyperaemia	2 (2%)	2 (3%)
Punctate keratitis	2 (2%)	1 (2%)
Conjunctival oedema	2 (2%)	0
Meibomianitis	2 (2%)	0
Anterior capsule contraction	2 (2%)	0
Chalazion	2 (2%)	0
Eye irritation	2 (2%)	0
Eye pruritus	2 (2%)	0
Eyelid ptosis	2 (2%)	0
Photopsia	2 (2%)	0
Vision blurred	2 (2%)	0
Non-ocular		
Headache	5 (5%)	2 (3%)

[a] Includes intraocular pressure increased and ocular hypertension [b] Defined as not occurring on the day of the injection procedure, or occurring on the day of the injection procedure and not resolving the same day [c] Includes cataract, cataract cortical, and cataract subcapsular [d] Defined as occurring on the day of the injection procedure and resolving the same day

USE IN SPECIAL POPULATIONS

8.1 Pregnancy Risk Summary There are no adequate and well-controlled studies with XIPERE® in pregnant women to inform drug-associated risks. In animal reproductive studies from the published literature, topical ocular administration of corticosteroids has been shown to produce teratogenicity at clinically relevant doses. There is negligible systemic XIPERE® exposure following suprachoroidal injection [see Clinical Pharmacology (12.3)]. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Animal Data Animal reproduction studies using XIPERE® have not been conducted. In animal reproductive studies from the published literature, topical ocular administration of corticosteroids to pregnant mice and rabbits during organogenesis has been shown to produce cleft palate, embryofetal death, herniated abdominal viscera, hypoplastic kidneys and craniofacial malformations.

8.2 Lactation Risk Summary It is not known whether ocular administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for XIPERE® and any potential adverse effects on the breastfed infant from XIPERE®. There are no data on the effects of XIPERE® on milk production.

8.4 Pediatric Use Safety and effectiveness of XIPERE® in pediatric patients have not been established.

8.5 Geriatric Use No overall differences in safety or effectiveness have been observed between elderly and younger patients following XIPERE® administration.

NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis No information is available on the carcinogenic potential of triamcinolone acetonide.

Mutagenesis No information is available on the mutagenic potential of triamcinolone acetonide.

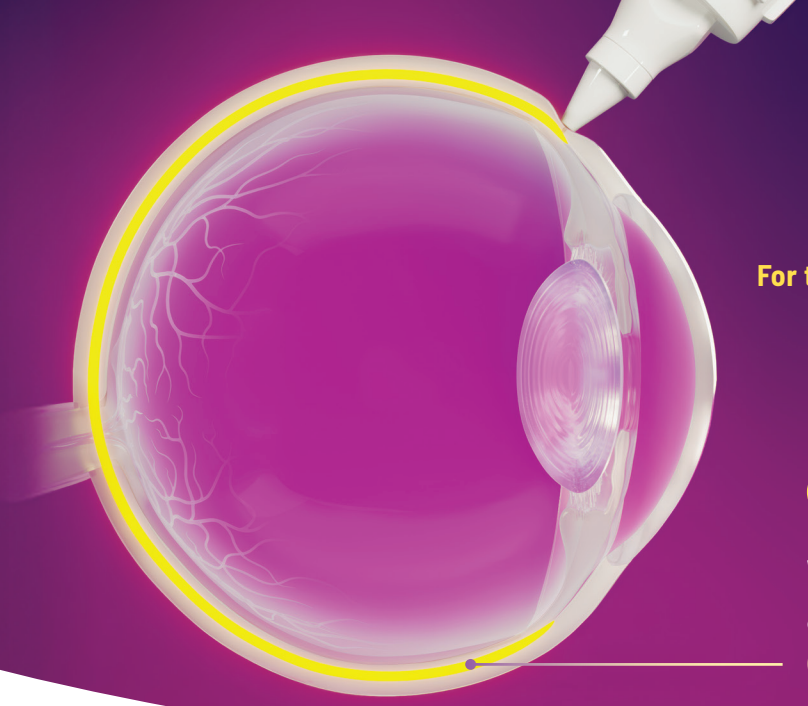
Fertility No information is available on the effect of triamcinolone acetonide on fertility.

Manufactured for: Clearside Biomedical, Inc.
900 North Point Parkway, Suite 200
Alpharetta, GA 30005 www.clearsidebio.com/patents

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XIPERE®
(triamcinolone acetonide injectable suspension) 40 mg/mL

For treatment of uveitic macular edema

CONTAINED & SUSTAINED.

With proven durability supported by clinical trials and real-world evidence,* **ONLY XIPERE® delivers treatment via the suprachoroidal space**[1-4]

In pivotal trial PEACHTREE, XIPERE®
SIGNIFICANTLY IMPROVED BCVA BY ≥15 ETDRS LETTERS AND REDUCED CST at Week 24[1,2,5]

In extension study MAGNOLIA and in the IRIS® Registry*
ELEVATION IN IOP WAS LOW OVER THE 48-WEEK PERIOD[2,6]

~88% of XIPERE®-treated patients in the IRIS® Registry had
NO NEED FOR RESCUE BY WEEK 24[2*]

PEACHTREE was a Phase 3 masked, randomized trial including 160 patients. MAGNOLIA was a multicenter, non-interventional extension study including 33 patients.

*The results of real-world studies should be considered in the context of the limitations of this type of evidence. While these findings provide insights into the real-world performance of XIPERE®, they may not be directly comparable to results from randomized controlled trials.

Visit XIPERE.COM for additional data and full study design

BCVA=best-corrected visual acuity; CST=central subfield thickness; ETDRS=Early Treatment Diabetic Retinopathy Study; IOP=intraocular pressure; IRIS=Intelligent Research in Sight.

Indication

XIPERE® (triamcinolone acetonide injectable suspension) for suprachoroidal use is a corticosteroid indicated for the treatment of macular edema associated with uveitis.

Important Safety Information

Patients should be monitored following injection for elevated intraocular pressure. See Dosage and Administration instructions in full Prescribing Information.

- XIPERE® is contraindicated in patients with **active or suspected ocular or periocular infections** including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
- XIPERE® is contraindicated in patients with known **hypersensitivity to triamcinolone acetonide** or any other components of this product.
- Use of corticosteroids may produce cataracts, increased intraocular pressure, and glaucoma. Use of corticosteroids may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses, and should be used cautiously in patients with a history of ocular herpes simplex.
- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia can occur following administration of a corticosteroid. Monitor patients for these conditions with chronic use.
- In controlled studies, the most common ocular adverse reactions were increased ocular pressure, non-acute (14%), eye pain, non-acute (12%), cataract (7%), increased intraocular pressure, acute (6%), vitreous detachment (5%), injection site pain (4%), conjunctival hemorrhage (4%), visual acuity reduced (4%), dry eye (3%), eye pain, acute (3%), photophobia (3%), and vitreous floaters (3%), and in 2% of patients: uveitis, conjunctival hyperaemia, punctate keratitis, conjunctival oedema, meibomianitis, anterior capsule contraction, chalazion, eye irritation, eye pruritus, eyelid ptosis, photopsia, and vision blurred.

  The most common non-ocular adverse event was headache (5%).
- Corticosteroids should be used during pregnancy or nursing only if the potential benefit justifies the potential risk to the fetus or nursing infant.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on adjacent page.

References: 1. XIPERE® [prescribing information]. Alpharetta, GA: Clearside Biomedical, Inc. **2.** Singer M, et al. Presented at: 57th Annual Retina Society Scientific Meeting. September 11-15, 2024; Lisbon, Portugal. **3.** Rai Udo J, et al. *Drug Discov Today.* 2015;20(4):491-495. **4.** Chiang B, Jung JH, Prausnitz MR. *Adv Drug Deliv Rev.* 2018;126:58-66. **5.** Yeh S, et al. *Ophthalmology.* 2020;127(7):948-955. **6.** Khurana RN, Merrill P, Yeh S, et al. *Br J Ophthalmol.* 2022;106(8):1139-1144.

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