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AS DEMONSTRATED IN PHASE 3 CLINICAL TRIALS

INDICATIONS AND IMPORTANT SAFETY INFORMATION
EYLEA® (aflibercept) Injection 2 mg (0.05 mL) is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

CONTRAINDICATIONS
• EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS
• Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
• Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
• There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the EYLEA group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

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REGENERON
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777 Old Saw Mill River Road, Tarrytown, NY 10591
Trust ≈8 Years of Extensive Clinical Experience and the Integrity of Data From Large, Well-Controlled Trials

EYLEA IS THE
#1 PRESCRIBED ANTI-VEGF FDA APPROVED FOR WET AMD, DME, AND MEFVRO1,*

≈9 MILLION DOSES ADMINISTERED TO
≈790,000 EYES TREATED SINCE LAUNCH1,2

8 PHASE 3 CLINICAL TRIALS INCLUDING MORE THAN 3000 EYLEA-TREATED PATIENTS STUDIED ACROSS ALL APPROVED INDICATIONS1

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ADVERSE REACTIONS

• Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
• The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Please see Brief Summary of Prescribing Information on the following page.


anti-VEGF = anti–vascular endothelial growth factor; AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema; MEFVRO = Macular Edema following Retinal Vein Occlusion.

≈8 YEARS OF REAL-WORLD EXPERIENCE1

≈8 YEAR OF REAL-WORLD EXPERIENCE

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EYLEA® (afibercept) Injection For Intravitreal Injection


anti-VEGF = anti–vascular endothelial growth factor; AMD = Age-related Macular Degeneration; DME = Diabetic Macular Edema; MEFVRO = Macular Edema following Retinal Vein Occlusion.
BRIEF SUMMARY—Please see the EYLEA full Prescribing Information available on HCP.EYLEA.US for additional product information.

1 INDICATIONS AND USES

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of:

Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR).

2 CONTRAINDICATIONS

1. Ocular or Periocular Infections

EYLEA is contraindicated in patients with active ocular or periocular infections.

2. Active Intravitreal Inflammation

EYLEA is contraindicated in patients with active intravitreal inflammation.

3. Hypersensitivity

EYLEA is contraindicated in patients with known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, severe anaphylactic/anaphylactoid reactions, or severe intravitreal inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Thromboembolic Events

There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including with EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (12 out of 662) in the combined group of patients treated with EYLEA compared with 1.5% (9 out of 592) in patients treated with ranibizumab; through 96 weeks, the incidence was 5.3% (26 out of 497) in the combined group of patients treated with EYLEA compared with 2.3% (8 out of 346) in the control group; from baseline to week 100, the incidence was 6.4% (17 out of 592) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

• Hypersensitivity (see Contraindications (4.2))
• Endophthalmitis and retinal detachments (see Warnings and Precautions (5.3))
• Intraocular inflammation (see Warnings and Precautions (5.3)).

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 other clinical trials of the same or another drug and may not reflect the rates observed in practice.

A total of 690 patients treated with EYLEA contributed to the safety population in eight phase 3 studies. Among those, 237 patients were treated with the recommended dose of 2 mg. Serious adverse reactions related to the injection procedure have occurred in <0.1% of patients treated with EYLEA including endophthalmitis; and retinal detachment. The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for an immune response in patients treated with EYLEA. The immunogenicity data reflect the percentage of patients whose results who would be considered positive for antibodies to EYLEA in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications, and underlying disease state. Immunogenicity may be an indicator that the immune system is responding to the drug. All antibodies are not necessarily clinically relevant. The majority of patients who develop antibodies do not appear to suffer a clinical adverse event associated with these antibodies.

6.3 Cataract

Cataracts may develop in patients taking EYLEA. In most cases, cataracts do not appear to be drug-related; however, patients should have a yearly dilated eye examination and be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately (see Patient Counseling Information (2.7)).

6.4 Ocular or Periocular Infections

EYLEA is contraindicated in patients with ocular or periocular infections.

7 ADVERSE REACTIONS

7.1 Clinical Trials Experience

7.2 Postmarketing Experience

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Antibody production and positive tests for anti-drug antibodies have occurred in patients treated with EYLEA. Anti-drug antibodies were detected in 12.8% of patients treated with EYLEA compared with 0.12% of patients treated with placebo. Anti-drug antibodies did not interfere with the sensitivity or specificity of assays to detect aflibercept.

8.2 Lactation

There are no data on the excretion of aflibercept in human milk. The potential for human milk effects with aflibercept is unknown. The decision to use EYLEA in a nursing woman must be individualized after consideration of the importance of the drug to the mother.

8.3 Pediatric Use

The safety and effectiveness of EYLEA in pediatric patients have not been established.

8.4 Geriatric Use

EYLEA has not been studied in patients ≥75 years of age. Because of the potential for decreased metabolic clearance, reduced renal function, and increased sensitivity to the effects of EYLEA, the dosing of EYLEA should be individualized in patients ≥75 years of age.

9 DOSAGE AND ADMINISTRATION

9.1 Administration

The recommended dose of EYLEA for patients treated with EYLEA is 2 mg intravitreal injection (see Indications and Usage (1)).

9.2 Route of Administration

EYLEA is administered to the vitreous cavity by a single intravitreal injection.

9.3 Monitoring

9.4 Monitoring of Treatment Response

9.5 Recurrence of Eye Disease

9.6 Postmarketing Experience

9.7 Information for Patients

10 REPRODUCIBILITY

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Regeneron Pharmaceuticals, Inc.

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Tarrytown, NY 10591

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20 CLINICAL STUDIES

20.1 Macular Edema Following Retinal Vein Occlusion (RVO)

20.2 Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)
You’ve probably heard quite a bit lately about private equity firms and their increasing interest in acquiring retina practices. There’s still some hesitation and skepticism regarding deals with private equity firms, and as with any business relationship, there are risks—but there are also may be some rewards. Now that several high-profile retina practices have entered into private equity deals, it is time to take another look at the topic.

In this issue’s feature article, Steven Madreperla, MD, PhD, explores private equity in the medical industry, addressing both the benefits and potential concerns of a private equity deal, and encourages physicians to consider both sides. The key to any successful business transaction is to make sure that both parties are on the same page and that all terms and negotiations are handled fairly and efficiently.

This issue also includes articles on the potential medico-legal risks of prescribing off-label drugs, how physicians can protect themselves from fraud allegations, and how to perfect your practice’s revenue cycle management.

And as we near the end of 2019, it’s never too early to start getting your taxes ready. Learn best practices for preparing your year-end taxes effectively and get recommendations on estate planning and finding out if your practice is eligible for certain business deductions.

ALAN RUBY, MD
SECTION EDITOR

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Eyetube
Anti-VEGF injections play a prominent role in retina practice, and receiving prompt payment for these expensive drugs is vital for your practice’s fiscal health. At prices approaching $2,000 per dose for some medications for the treatment of age-related macular degeneration (AMD) and other conditions, it doesn’t take many unreimbursed claims or delayed payments to start affecting your practice’s bottom line.

Financial issues due to drug mismanagement can be avoided in your practice by maintaining an efficient revenue cycle. Reviewing your internal revenue cycle management (RCM) and monitoring it for potential problems can help you to maximize profitability in encounters requiring medication.

RCM starts when you code an encounter and ends when you are fully reimbursed for those services. When a patient encounter includes the administration of high-cost medications, the stakes are high, and RCM deserves extra scrutiny. Delay in reimbursement for drugs can affect your practice’s profitability, as expenses may be paid prior to income receipt.

**RCM GOALS**

The goal of RCM is to obtain prompt payment. RCM for patient encounters that require the administration of medication may be more complex than for visits with no medication involved. Your practice protocol should have clear goals and should anticipate potential barriers to prompt payment.

RCM for encounters requiring medication should start with a routine review of each claim’s status and should be designed to promptly resolve issues as they arise. By learning the unique challenges presented by your subspecialty or by particular insurance carriers, you can outline a protocol that will help you identify and possibly avoid future problems.

**KNOW YOUR PAYERS**

Gain a comprehensive understanding of each insurance carrier’s policies regarding intravitreal injection. Key areas include policies related to prior authorization (PA), step therapy, treatment frequency, specific tests needed to establish medical necessity, and approved diagnosis codes per medication. Medicare Part B policies for each Medicare Administrative Contractor can be found at aao.org/lcds.

**AT A GLANCE**

- Revenue cycle management (RCM) is important in managing the finances associated with expensive drugs.
- Understanding all the sources of revenue that contribute to full reimbursement is key to maintaining a healthy practice.
- Staying flexible will help you adjust your RCM protocol as changes occur.
CORRECT CODING AND BEYOND

RCM begins with coding the injection encounter and promptly submitting to an insurance carrier a claim that meets all coding guidelines. To ensure accuracy, verify that your coding meets payer guidelines by using an internal injection coding checklist for each insurance carrier. This resource can be created from insurance policies. You can also rely on the Coding for Injectable Drugs guidelines found at aao.org/practice-management/coding/injectable-drugs or refer to my article published earlier this year in Retina Today, “Successfully Coding Retina Injectable Drugs,” which can be found at bit.ly/Woodke1119.

An internal review of your inventory log, chart documentation, and coding is key for RCM. The medication entered on the inventory log per patient should match the chart documentation and insurance claim. This correct coding audit will confirm that the claim is accurate and consistent with all documentation. Only after the claim has been verified should it be submitted to the insurance carrier. A high-level review should also be completed monthly to confirm that inventory, documentation, and coding all agree.

Conducting this review process will help you to confirm that each component of the medication claim is correct. Potential errors in the process can include incorrect recording of medication, wastage, units, or diagnosis. The consequences of these errors are outlined in Table 1.

<table>
<thead>
<tr>
<th>TABLE 1. EXAMPLES OF POTENTIAL ERRORS</th>
</tr>
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<tbody>
<tr>
<td><strong>Inventory Log</strong></td>
</tr>
<tr>
<td>Aflibercept vial dispensed</td>
</tr>
<tr>
<td>Ranibizumab 0.3 mg dispensed</td>
</tr>
<tr>
<td>Aflibercept vial dispensed Patient: John Smith</td>
</tr>
<tr>
<td>Ranibizumab 0.5 mg OD</td>
</tr>
<tr>
<td>Triesence 40 mg vial</td>
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</tbody>
</table>

Table adapted from The Profitable Retina Practice: Medication Inventory Management (San Francisco: AAO.) Find online at aao.org/store.

MONITOR AGING REPORTS

Essential to RCM is monitoring your accounts receivable aging reports. For a retina practice, this requires a focused review of the claims related to drug reimbursement. Promptly identifying delays in drug payments allows timely resolutions.

Reviews may reveal insurance delays related to complications of PA or medical record submission. Internal problems may include practice management system glitches that occur when sending claims or clearinghouse scrub edits that are not resolved and delay submission. Creating and monitoring various reports that identify all medication claims filtered by insurance carrier, specific drugs, or date of service will allow a comprehensive analysis of your medication accounts receivable.

INSURANCE DENIALS

When medication claims are denied by an insurance carrier, a quick analysis of the cause is necessary in order to find a solution. The denial may be due to an internal error, a claim submitted with deficiencies, or an external error related to insurance claim processing.

Internal errors may include incorrect units for medication, inaccurate ICD-10 coding (eg, dry AMD instead of wet AMD), an ICD-10 code not supported by medical necessity or drug indication, injection sooner than 28 days, a missing PA, a step therapy protocol that was not followed, or unsubmitted medical records. External errors can include an insurance carrier not following its own policy, an incorrect denial of a claim (requiring an appeal), issues with patient eligibility or coordination of benefits, a computer glitch, or a delayed claim with no response.

Regardless of the reason for the claim denial, timely response to resolve the issue is necessary. Create a system to address denials related to medication claims to facilitate resolution. See Table 2 for an example of a checklist.

FULL REIMBURSEMENT

The revenue cycle is complete when full reimbursement is received for a medication claim. This is achieved when the total allowable for the drug is collected from any or all of the following: primary and secondary insurance carriers, the patient’s deductible or coinsurance, and patient assistance programs (PAPs). Ensuring that all money is collected may require monitoring of these various payment sources.

Full reimbursement occurs only when the correct allowable has been received from all payment sources.
A comprehensive analysis of the allowable per medication and insurance carrier should confirm the contracted rate. Medicare Part B allowables are based on the CMS average sales price (ASP) drug pricing files. Payment limits are calculated at 106% of the ASP. They are updated quarterly and published at CMS.gov, where the medications are listed by HCPCS codes (ie, J-codes), and published data on the payment limit and the dosage per unit are included.

To understand the relationship between dosing, units, and allowables, it may be useful to use an example. In the fourth quarter of 2019, the allowable for 0.1 mg, or 1 unit, of ranibizumab (Lucentis, Genentech) is $352.174. When injecting 0.5 mg, or 5 units, of ranibizumab, the total allowable is $1,760.87.

Medicare Advantage (MA) plans or commercial payers may reimburse based on the CMS ASP drug pricing files or based on a different contracted rate. These may be outlined in the payer contract in a number of ways, including:

- 100% of current CMS ASP drug pricing files;
- A higher percentage of CMS ASP drug pricing files;
- A percentage of the usual and customary billed fee; or
- A carve-out contract rate per J-Code.

After the contracted allowable per payer has been identified, a comprehensive report of the actual payments posted can be verified. This can be monitored during the payment process as well.

After the primary payment is received, any remaining balance is transferred to a secondary insurance carrier, the patient, or a PAP. Monitoring this RCM step is critical to ensure that full reimbursement is obtained. A delay in the claim being sent to the secondary insurance or the request for payment being sent to the PAP will affect the accounts receivable aging. Careful attention to targeted reports of each step, prompting action as appropriate, will help you to achieve full reimbursement in a timely manner.

CONTINUOUS PROCESS IMPROVEMENT

As you refine your RCM process focusing on medication claims, new challenges will occur, prompting further changes to your workflow. New, detailed reports that may require routine reviews will be created. A specific insurance carrier may change its policies without warning, which in turn will demand internal process changes. When protocol updates occur, communication and training with all stakeholders in the practice is required to maintain an efficient RCM. A commitment to the scrutiny of the accounts receivable will help you to maintain and even improve medication profitability in your practice.

JOY WOODKE, COE, OCS, OCR
- Coding and Practice Management Executive, American Academy of Ophthalmology, San Francisco
- jwoodke@aoa.org
- Financial disclosure: None

<table>
<thead>
<tr>
<th>TABLE 2. WHAT TO DO WHEN A CLAIM IS DENIED</th>
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<tbody>
<tr>
<td>• Identify the reason for the denial.</td>
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<tr>
<td>• Correct the insurance claim, if necessary.</td>
</tr>
<tr>
<td>• Appeal the claim.</td>
</tr>
<tr>
<td>• Monitor insurance response.</td>
</tr>
<tr>
<td>• Confirm appropriate collection of payment.</td>
</tr>
<tr>
<td>• Track internal denials and trends.</td>
</tr>
<tr>
<td>• Train staff and physicians on internal changes to avoid denials.</td>
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The use of a drug for a purpose or indication that has not been approved by the US FDA is referred to as an off-label use of that drug. It is estimated that more than 20% of prescribed medications are given for indications not approved by the FDA based on large prospective randomized clinical trials.1 The Food, Drug, and Cosmetic Act of 1938 required only that new drugs be safe. It was not until the Kefauver-Harris Amendment to the act was passed in 1962 that the FDA also required evidence that drugs be effective.

As a result of these policies, off-label drug use requires not only that the safety of the drug has been demonstrated, but also that efficacy for the off-label indication has been shown in multiple, peer-reviewed studies, and that the treatment conforms to the standard of care for the indication for which it is being used. (Use of off-label drugs for research purposes have a special exemption, which will be discussed below.)

The current widespread use of drugs for off-label indications potentially exposes prescribing physicians to legal risks that are not carried by on-label uses. This article addresses some of the legal implications of off-label drug use in ophthalmology and safeguards that prescribing physicians can take to reduce their risk of litigation.

**CLINICAL TRIAL DATA NEEDED**

Does off-label use of a drug inherently subject the prescriber to an increased risk of litigation solely on the basis of its off-label status? This depends on a number of factors.

As is the case in prescribing any drug, the physician has the legal responsibility to discuss with the patient the risks, benefits of, and alternatives to the medication, and to adhere to the standard of care. When a drug is used for a labeled indication, the physician has the benefit of relying on large prospective studies that have demonstrated efficacy and safety and that were used to gain FDA approval for the prescribed indication for the drug. In prescribing an off-label drug, the physician still must be able to cite peer-reviewed clinical data to demonstrate the safety and efficacy of the off-label use of the medication.

To date, no court decision has mandated that a physician must disclose to a patient that a drug is being used off-label. However, through the informed consent process, the physician must demonstrate that he or she is meeting the standard of care in prescribing the off-label medication. As part of this process, the physician must demonstrate evidence of the acceptance of the off-label use in the medical community as a treatment for the off-label indication for which it is being used.

When a lawsuit is brought, in order for the complainant to prove negligence, it must be demonstrated that the physician deviated from the standard of care, independent of whether the medication was off-label.

**INVESTIGATIONAL USE**

One area in which physicians run the risk of legal liability is in the use of an off-label drug for investigational purposes. Investigational use differs from clinical off-label use and is subject to an entirely different set of regulations. Investigational use implies the use of a medication in the context of a clinical study. In a study setting, the physician may be required to submit a study protocol for approval by an institutional review board. This is different from off-

**AT A GLANCE**

- It is estimated that up to one-fifth of prescriptions are given for indications not approved by the US FDA.
- Medicolegal risk from off-label use depends on a number of factors, including the existence of evidence for the safety and efficacy of the drug for the intended indication.
- Use of a certified compounding pharmacy is vital for off-label medication use.
label use of a medication for the clinical treatment of a particular patient based on previously demonstrated off-label indications of the drug. FDA regulations allow the off-label use of medications in the treatment of patients, but not the off-label use of a medication for investigational purposes (unless as part of a research protocol).

COMPOUNDING RISKS

One of the greatest legal risks that physicians face in using off-label drugs is potential liability from using a compounding pharmacy to prepare a drug for off-label use. The most common example of this in ophthalmology is the widespread use of bevacizumab (Avastin, Genentech) for the treatment of a wide variety of retinal disorders. Compounded drugs are not FDA approved; that is, the FDA does not verify their safety or efficacy.

Unfortunately, there have been many episodes of contamination of compounded drugs. The most serious in recent memory was the fungal contamination of steroid compounds used in the treatment of spinal and joint disease, resulting in an outbreak of fungal meningitis.2

Although this outbreak received a high degree of attention from the public, it was by no means an isolated event. There have been numerous instances of contamination, mislabeling, and poor-quality preparation of compounded drugs that have resulted in the closings of compounding pharmacies or recalls of dispensed medications. Contaminated batches of bevacizumab have been recalled from many compounding pharmacies, and some such cases of contamination have resulted in patients being blinded. Liability in these instances has largely fallen on the compounding pharmacies. Courts have generally ruled that, as long as the physician met the standard of care and obtained adequate informed consent, no negligence occurred on the physician’s part. In instances in which the ophthalmologist was found at fault, there have usually been other circumstances around the use of the off-label drug that resulted in the guilty verdict, such as inadequate preparation of the injection site, puncturing a single-dose vial multiple times, or use of the drug in conjunction with other drugs in a single syringe.3

Physicians must be sure that the compounding pharmacies they use are certified as approved providers of compounded medications as defined under an FDA guidance document.4 Physicians should contract only with facilities that have certification to provide the off-label drug. Additionally, physicians should maintain close working relationships with these pharmacies to ensure prompt notification of any issues at the compounding facility that may affect the quality of the manufactured drug. Failure to adhere to these safeguards may result in the physician being found negligent in the event that a drug is contaminated.

BILATERAL INJECTION

Another issue that deserves attention is the use of bilateral injections of an off-label drug in the treatment of retinal disorders. Many physicians perform same-day bilateral injections to reduce the treatment burden on patients with bilateral retinal diseases. Multiple studies have shown no significant difference in the incidence of local complications resulting from bilateral versus unilateral injections of anti-VEGF drugs in the treatment of retinal diseases.

But what is the increased liability if a patient were to develop endophthalmitis in both eyes as a result of injection of a contaminated compounded drug? There have been no reports of contamination of the FDA-approved anti-VEGF intravitreal injections (ie, ranibizumab [Lucentis, Genentech] and aflibercept [Eylea, Regeneron]) for the treatment of neovascular age-related macular degeneration. However, there have been numerous reports of bacterial or fungal contamination of compounded bevacizumab. Physicians may want to consider whether they are willing to risk performing bilateral injections of compounded off-label drugs, given the small but not insignificant risk of drug contamination.

CONCLUSION

The off-label use of a medication may present the physician with increased legal risks. Most of these can be mitigated by adhering to guidelines that the physician should follow regardless of whether the drug or therapy is labeled for the intended indication or not.

The best protection for the physician is to adhere to the standard of care and obtain informed consent from the patient before administering the drug for an off-label indication. In addition, the use of a certified compounding pharmacy is crucial to reduce the risk of drug contamination that may result in harm to the patient.

By adhering to these general guidelines, physicians can continue to use drugs for off-label indications in the treatment of their patients while protecting themselves from increased legal risks that may result from their use.
There is a lot of discussion lately about private equity (PE) investment in ophthalmology. The wider issue that more accurately captures the motivation behind this phenomenon currently occurring in ophthalmology, other subspecialties, and primary health care, is consolidation.

Consolidation is happening in many nonphysician vertical markets as well, including the insurance industry, pharmacy benefit management organizations, pharmacies, and hospital systems. Motivations for consolidation in these sectors may vary, but the underlying reasoning is that consolidation allows businesses to improve their services and more effectively compete in their markets. The same is true in ophthalmology.

Consolidation of businesses requires access to capital and expertise. This is where PE investment enters the picture. Generally, it is not PE that is driving the process of consolidation; rather, it is practice owners who see that PE-supported...
consolidation offers them a way to continue to have access to patients while being part of an organization that can compete with others in their markets.

Fortunately for ophthalmology, PE firms have been supporting this kind of activity in other multisite medical specialties for years, and many PE firms are both interested and experienced in providing the expertise required to facilitate consolidation in ophthalmology.

**AT A GLANCE**

- Practices interested in consolidation should carefully evaluate the mission and vision of the investing entity.
- Consolidation can allow businesses to improve their services and more effectively compete in their markets.
- Risk is unavoidable. Risk exists in both choosing a consolidation partner, as one may choose an underperforming firm, and in choosing not to consolidate, particularly for practices in competitive markets.

**Streamlined Management**

Human resource management is a difficult and time-consuming process that can be improved upon and streamlined in a consolidated entity. Increased scale allows standardization of training and compliance testing, and it can improve scheduling and availability of backup staff. Large consolidated entities can optimize back-office functions such as billing and collections, facility operations, and supply chain management. To the extent that physicians were previously involved in managing those functions, delegating these tasks to professional management teams frees the physicians to direct that energy and time to patient care.

Information technology and software management takes additional time, energy, and resources from physician owners, and the expertise and staff required to take advantage of modern data analytics exceeds the capacity of most clinical practices. Consolidated entities with dedicated resources and expertise can provide data-driven analytics and solutions for a range of problems, from minimizing patient wait time to understanding geographic disease burden so that the practice can optimally deploy its resources to serve the community.

Many ophthalmologists now practicing in multiphysician entities have watched their practices grow over the years and have experienced the benefits and challenges that come with a larger organization. As these practices grew, the tasks previously performed by doctors were shifted to managers who helped to optimize certain aspects of the practice.

**Optimized Compliance**

Medical practices are subject to intense and increasing regulatory requirements, the challenges of meeting performance goals for government programs, and a landscape of changing laws that apply to practice activities. Maintaining adequate compliance and optimizing government program performance are increasingly difficult tasks for small practices, whereas larger entities are able to employ teams dedicated to compliance and the optimization of program performance.

**COMMON CONCERNS**

- With any new venture, there are bound to be concerns. Some of the most frequently expressed concerns are those addressed below.

**Loss of Control**

Physicians worry that joining a consolidated entity will result in loss of control of their practice. Increased scale always coincides with loss of control to some extent. Many ophthalmologists have already experienced this as their clinical practices grew and more doctors became involved in decision-making. Although increased scale is associated with an increase in meetings and organizational bureaucracy, most doctors would probably agree that their practices have improved as they’ve grown.

The problem is that growing by adding one, two, or even five doctors per year, as was sufficient in the past, is unlikely to create the scale necessary to thrive in today’s competitive health care markets. What is required is an organizational structure that can grow by consolidation of existing practices, with the ability to build the infrastructure and scale at sufficient pace.

**Inferior Patient Care**

Will the entrance of PE into ophthalmology (or medicine in general) influence medical decision-making and somehow lead to inferior patient care in the name of profitability? This is a noble and not unwarranted concern, but a careful consideration...
of facts and circumstances can offer significant reassurance.

It is important to note that most states prohibit direct ownership of a medical practice by a nonphysician. Therefore, PE involvement is generally limited to an ownership interest in an administrative service organization (ASO) that provides nonclinical services to a medical practice or practices. Because of this limitation, PE firms and their associated ASOs do not control the clinical decision-making of the physicians in the practice. A properly designed organizational structure segregates clinical decision-making and related matters to boards or committees of physicians within the medical practice.

Additionally, like any doctor-owner, a good PE firm is interested in building a great business. The firm understands that what defines a great business is the service it provides. Thus, PE firms should have no interest in investing in an organization that provides poor care.

Furthermore, most PE sponsors in our space do not directly perform operational functions in the ASO; rather, they play a supportive role in building the organization and allow the management team to run the day-to-day business. In a properly designed structure, physicians in the medical practice help guide the management team to set priorities and goals.

PE-Backed Transactions

When people raise concern about PE-backed transactions, they are referring to the need of the PE firm to sell its interest in the ASO, on average, within 5 years after the initial investment. The concern is that, at the time of the second transaction, the doctor in the practice will have no say in who buys the practice, and the buyer could be an undesirable partner. In reality, in a properly structured organization, physicians have significant representation on the board of the ASO—granted, often not majority representation—and will have significant influence in determining the buyer.

In many cases, the buyer is another PE firm, investing from a larger fund with a mandate to invest in larger companies. Most likely, these larger PE firms are interested in having an ownership position in the entity because the firm believes in the mission of that practice. The PE firm often intends for the same management team to continue to execute the same plan that existed prior to the transaction.

Nobody’s Perfect

Questions have been raised regarding the operations of some PE-backed ASOs that appear to promote medical activities that emphasize profitability over patient care. However, these same types of behaviors have been seen in doctor-owned medical practices without the involvement of a PE partner.

Any practice that is looking to affiliate with a PE group, a PE-backed ASO, or any consolidated entity should carefully evaluate the mission and vision of the group and confirm those impressions with significant due diligence.

How is Value Created?

Some physicians may not understand how value is created in the consolidation of medical practices. This misunderstanding can foster the concern that a PE partner would push a profit-first approach that leads to inferior patient care. In fact, the simple act of one small group joining a larger group creates inherent value greater than the sum of both unaffiliated entities.

In a consolidated entity, earnings are less likely to be disrupted if, for instance, one physician is suddenly unable to practice. In an unaffiliated practice, revenue would decrease immediately and would likely take significant time to recover, whereas in a group of 100 doctors, it would be relatively easy to provide coverage for the absent doctor until a replacement could be secured. Revenue would not be affected. More important, patient care would not be interrupted.

Consolidation creates value for all stakeholders, and that value increases along with the quality and availability of care. It is not likely to be the business plan of a PE-backed ASO to have its associated physicians work more hours than they did in the past or adopt clinically inferior practices to increase profits. PE firms will generally want to exit their investment in the ASO at some point, and they will want the clinical practice and ASO to be highly regarded at that time.

PE firms and physicians are generally aligned in the desire to provide excellent clinical care. The value that these entities can return to their investors is created by many features of the consolidation process and is enhanced by the reputation that the organization garners for providing excellent care.

Risk is Inevitable

For ophthalmology practices today, some risk is unavoidable. Risk exists both in choosing a consolidation partner, as one may choose an underperforming firm, and in choosing not to consolidate, as one may lose out in a competitive market.

Loss of control is relative. Maintaining control of a practice does not mean much if remaining independent leads to a negative outcome for the practice, such as losing access to patients.

Fortunately, PE firms are willing to invest their capital to partner with ophthalmology practices that have determined consolidation to be their best opportunity to remain competitive in their markets, enjoy continued access to patients, and focus on providing great care for those patients.

Steven Madreperla, MD, PhD
Vitreoretinal Surgeon, NJRetina, New Jersey
Financial disclosure: President and CEO
(Associated Retinal Consultants, LLC dba NJRetina; Prism Vision Group)
FRAUD AND ABUSE: A NEW FOCUS ON PHYSICIANS

Ophthalmologists can protect themselves by being familiar with relevant laws and documenting their industry consulting efforts.

AN INTERVIEW WITH ALLISON W. SHUREN, JD; BY ROCHELLE NATALONI, CONTRIBUTING WRITER

recently, federal agencies have stepped up their efforts to enforce health care fraud and abuse statutes by going after physicians’ personal finances. According to Allison W. Shuren, JD, it has been reported that there was a threefold increase in 2017 in the number of instances in which physicians and other individuals were personally responsible in settlements under the False Claims Act stemming from government investigations. This increase is due to a greater willingness in the US Department of Justice and the offices of US Attorneys to hold individual physicians financially accountable for their alleged fraudulent or abusive actions.

RT Business Matters discussed this trend with Ms. Shuren, a chair of the Life Sciences and Healthcare Regulatory Group at the law firm Arnold & Porter, where she represents clients in government investigations and qui tam actions involving the False Claims Act, the Anti-Kickback Statute, the Physician Self-Referral Statute, and health care fraud allegations.

RTBM: You reported that there has been a threefold increase in cases in which physicians are being held personally financially responsible for fraud and abuse violations carried out by their practices. Why is this on the rise?

Ms. Shuren: Historically, the government has steered away from holding individuals accountable for settlement amounts, instead assessing penalties against corporate entities, but this hasn’t led to any real decrease in the perceived levels of fraud and abuse in the system. Whistleblowers and their counsels have long advocated that, in order to achieve real behavioral change, individuals—not only corporate entities—must be held accountable. If physicians and others have personal wealth at stake, the reasoning goes, they will pay more attention to compliance with fraud and abuse laws.

RTBM: What is the difference between fraud and abuse, and why are they relevant to physicians?

Ms. Shuren: Fraud includes, for example, obtaining something of value through knowing misrepresentation, concealment of material facts, or offering or receiving something of value in return for ordering a particular item or service or for referring a patient. Abuse includes any practice that is not consistent with the goal of providing patients with services that are medically necessary, that meet professionally recognized standards, and that are fairly priced. Often, abuse cannot be differentiated categorically from fraud because the distinction between fraud and abuse depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other things. Physicians need to also be aware of so-called waste violations. Waste includes incurring unnecessary costs as a result of deficient management practices, systems, or controls—including shoddy bookkeeping and accounting.

IN THE KNOW

Federal Fraud and Abuse Laws Most Relevant to Physicians

- False Claims Act
- Anti-Kickback Statute
- Physician Self-Referral Statute, often known as the Stark Law
- Exclusion Authorities
- Civil Monetary Penalties Law
SOME PHYSICIANS BELIEVE THAT FREE LUNCHES, SUBSIDIZED TRIPS, AND GIFTS ARE INNOCUOUS, BUT RESEARCH SUGGESTS THAT THESE TYPES OF PERKS, IN CONJUNCTION WITH THE NATURAL DESIRE TO RECIPROCATE, CAN INFLUENCE PRESCRIBING PRACTICES AND GENERALLY AFFECT HOW PHYSICIANS ACT.

RTBM: What can ophthalmologists do to protect their assets?

Ms. Shuren: The best way physicians can protect themselves is to become familiar with the federal fraud and abuse laws that are most relevant to them: the False Claims Act; the Anti-Kickback Statute; the Physician Self-Referral Statute, often better known as the Stark Law for its author, Congressman Fortney “Pete” Stark; the Exclusion Authorities; and the Civil Monetary Penalties Law.

Violating the Anti-Kickback Statute carries stiff penalties. Violations can result in prison sentences and fines and penalties of up to $50,000 per kickback. Violations of the Anti-Kickback Statute also may trip the False Claims Act, which carries potential damages of up to three times the amount of the remuneration, plus penalties of between $11,181 and $22,363 per claim.

Additionally, physicians can be excluded from participation in the federal health care programs for violating the Anti-Kickback Statute. Sometimes these exclusions are referred to as a financial death sentence because excluded physicians may not receive payment for treating Medicare and Medicaid beneficiaries. Commercial payers typically drop excluded providers from their networks as well.

RTBM: How can ophthalmologists be sure to avoid violating the Anti-Kickback Statute?

Ms. Shuren: They should avoid situations that could be perceived as asking for or receiving any remuneration—basically anything of value—in exchange for referrals of federal health care program business.

This statute applies to both payers and recipients of kickbacks. Just offering a kickback could violate the law. The law prohibits obvious kickbacks, such as cash for referrals, as well as more subtle kickbacks, such as free rent, rent below fair market value, free clerical staff, or excessive compensation for medical directorships.

Numerous physicians have been sanctioned for allegedly selling their product loyalty to drug or device companies or other vendors. For example, an orthopedic surgeon who was accused of accepting kickbacks from a device manufacturer in exchange for preferentially using its artificial hip and knee joints recently paid $650,000 to settle the case against him.

RT: Is there an area in which ophthalmologists might be particularly vulnerable?

Ms. Shuren: Ophthalmologists should be careful when it comes to industry consulting fees. Some ophthalmologists are more closely involved with industry than others, but all physicians will encounter representatives of drug, device, and biologics manufacturers or other suppliers at some point in their careers. Some physicians believe that free lunches, subsidized trips, and gifts are innocuous, but research suggests that these types of perks, in conjunction with the natural desire to reciprocate, can influence prescribing practices and generally affect how physicians act.

RTBM: How can ophthalmologists who have consulting relationships with industry avoid being penalized?

Ms. Shuren: The key lies in careful record keeping. If a surgeon is collecting money from a company, he or she needs to be able to justify and support that a service was rendered. When we advise our physician clients, we stress that they must make sure that the company actually needs their consulting services and that the amount paid is fair market value for the services rendered.

Physicians’ collaboration with industry is important for product development and for science, so we are not suggesting that ophthalmologists should avoid consulting. What we’re saying is that both sides need to pay attention and do it in the right way. There must be documentation; the government demands record keeping on both sides. Under the Sunshine Act, companies must report what they pay physicians for consulting. As the recipients of these payments, physicians have a responsibility to keep track of the money they receive.

Lately, we have been working with several physician consultants. We try to help them understand how important this is and work with their staffs to develop spreadsheets to track and identify their consulting efforts. We stress that they need to be able to document, for instance, “Attended 4-hour advisory board at ASRS.” It doesn’t have to be long or too detailed—just accurate.

2019 YEAR-END TAX PLANNING TIPS

As this year draws to a close, it’s time to start getting ready to prepare your 2019 tax bill.

BY CAROLE C. FOOS, CPA; AND DAVID MANDELL, JD, MBA

Although many of you have just completed and filed your 2018 tax returns, it’s already time to look to the end of 2019 and take steps to reduce this year’s tax bill. Since 2018 was the first year that most provisions of the Tax Cuts and Jobs Act of 2017 were in effect, hopefully you have a better understanding of how the new tax law affected you and will continue to affect you for the 2019 tax year and beyond.

TAX DEDUCTIONS: CHOOSING BETWEEN STANDARD AND ITEMIZED

One of the biggest changes for 2018 individual filers was the reduced state and local income tax deduction, which is now capped at $10,000. This change, along with the increased standard deduction, led to many filers not itemizing deductions in 2018. If there’s a chance that you won’t itemize deductions in 2019 and will instead claim the standard deduction ($24,400 for married taxpayers filing jointly; $12,200 for single filers), consider how this will affect other deductions.

Charitable contributions are only deductible for taxpayers who itemize. You may want to consider bunching your charitable contributions to take full advantage in the years when you will itemize deductions. Donor-advised funds may be a consideration for taxpayers who want to make a larger contribution in a given year, but still have the charities benefit over several years. Also, take a look at your mortgage if you will no longer itemize. Because interest rates are still low, you can likely still earn more by investing assets in the market than what you’re paying in mortgage interest, even if you don’t get a tax deduction for the mortgage interest.

POSSIBLE DOUBLE DEDUCTION FOR PRACTICE OWNERS

Many of you found out the hard way that your pass-through business did not qualify for the new section 199A qualified business income (QBI) deduction. Medical practice owners whose individual taxable income was above certain threshold amounts were ineligible for the deduction because their organization was a specified service trade or business. Depending on how close your income was to those amounts, you may be able to reduce your income below the threshold by either implementing or enhancing your current qualified retirement plan (QRP). This can result in not only a deduction for your QRP contribution, but also the 20% QBI deduction. The combination of the two deductions often pays for much of the QRP cost.

The final regulations for section 199A did contain an example in which an outpatient surgery center was not a specified service trade or business. In the example, no physicians, nurses, or medical assistants were employed by the surgery center, and patients were only billed a facility fee by the surgery center. If you feel that your center might fit this example, discuss with your CPA whether you can take the QBI deduction this year or if there are steps you can take to become eligible for the deduction.

IS YOUR INVESTMENT PORTFOLIO DESIGNED FOR TAX SAVINGS?

Your investment portfolio provides ample opportunities for tax planning. Having a tax-efficient portfolio can save you thousands of dollars in taxes. Consider the timing of sales: A holding period of greater than 12 months allows you to pay long-term capital gains rates on the realized gain from a sale with a maximum rate of 20% versus a maximum rate of 37% on an investment that was held for less than a year. Be proactive in realizing losses to offset...
capital gains, and vice versa. A temporary dip in the stock market may be the time to realize some losses can be used to offset capital gains. If you find that you have net realized losses this year, sell some of the investments that have had tremendous gains over the past few years and then repurchase them at their higher price in order to both offset your losses and increase your basis in your current stocks.

It’s also a good time to evaluate which stocks you hold in which accounts. Brokerage accounts, Roth IRAs, and qualified plans are subject to various forms of taxation. It’s important to utilize the tax advantages of these tools to ensure they work for you in the most productive manner possible. Investment vehicles paying qualified dividends are preferred in a brokerage account, while it is generally preferable for qualified accounts to own high-yield bonds and corporate debt taxed at ordinary income rates. Work with your investment advisor to make sure your portfolio is properly positioned for tax efficiency.

**ESTATE PLANNING CONSIDERATIONS**

You may also want to think about your estate planning. The Tax Cuts and Jobs Act made the federal estate tax exemption $22.8 million for married couples in 2019, but that exemption amount will end in 2025. Before then, it might make sense to transfer some of your wealth to a trust for the benefit of your heirs. Assets that you know you won’t need in your lifetime can thus be protected against future estate tax increases and exemption reductions.

As Benjamin Franklin said, “Failing to plan is planning to fail.” Act now to protect your wealth and maximize your tax savings opportunities in 2019.

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Mr. Mandell is an attorney, consultant at the OJM Group, and author of more than a dozen books for doctors. To receive free print copies or e-book downloads of For Doctors Only: A Guide to Working Less and Building More and Wealth Management Made Simple, text RETINA to 555-888, or visit www.ojmbookstore.com and enter promotional code RETINA at checkout.

**Disclosure:**

- **CAROLE C. FOOS, CPA**
  - Partner, OJM Group, Cincinnati
  - carole@ojmgroup.com
  - Financial disclosure: Employee (OJM Group)

- **DAVID MANDELL, JD, MBA**
  - Partner, OJM Group, Cincinnati
  - david@ojmgroup.com
  - Financial disclosure: Employee (OJM Group)
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