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We ophthalmologists were given an incredible gift when the Centers for Medicare & Medicaid Services' (CMS) ruling removed the issue of not being able to balance bill for presbyopia-correcting, new-technology IOLs. Sufficient payment should encourage the development of a multitude of new lenses that will dramatically improve the quality of treatments for refractive surgery patients, in particular the treatment of presbyopia. Our actions in this new arena are currently under the microscope, however, so we must be careful about our charges for presbyopia-correcting IOLs.

BALANCE BILLING AND THE CMS' RULING

Balance billing occurs when a beneficiary is asked to pay the difference between the actual charge for a covered service and the amount that the health coverage provider has contractually agreed to accept as full payment for the covered service. Balance billing does not include the collection of copayments and deductibles. The practice of balance billing may result in providers breaching their agreements with third-party payors. There may also be violations of state insurance and consumer protection laws.

The CMS' ruling changed the way presbyopia-correcting, new-technology IOLs may be billed. The agency's rulings act as precedent to final opinions and orders as well as statements of policy and interpretation. The rulings shed light on ambiguous regulations and laws associated with Medicare, Medicaid, and private health insurances. The specific ruling that changed the way that ophthalmologists may bill for presbyopia-correcting IOLs was issued on May 3, 2005, and authored by Mark B. McClellan, the administrator for the CMS. The ruling concluded that additional services that are intended to correct presby-

opia are not considered covered services. Physicians may therefore bill and collect for these additional services without this practice being considered balance billing.

FAIR CHARGES

With flexibility in our billing practices, we still must ensure that our charges are fair and reasonable, and we must be able to document how our fees were determined. The Office of Inspector General (OIG) is responsible for protecting the integrity of the Department of Health and Human Services' programs as well as the health and welfare of the beneficiaries of those programs. The OIG performs this function through audits, investigations, and inspections, and it has made clear that it will investigate in particular those who appear to be abusing the privilege. Our ability to bill for additional services must represent real costs, including the actual time spent (eg, educating patients, surgery, follow-up) on these new IOL technologies.

Not only should we conduct a careful review of all costs in association with presbyopia-correcting lenses, but the actual expenses should be audited and the charges adjusted accordingly to show a good-faith effort to meet the conditions of our agreement with the CMS. Simply choosing a number without any documentation could open an individual to potential penalties—and jeopardize the privilege given to ophthalmology.

ANTITRUST VIOLATIONS

Because we now may bill Medicare patients for the additional services associated with presbyopia-correcting IOLs, we must be exceedingly watchful for antitrust violations related in any way to price fixing. The problem could be as simple as several independent groups casually discussing prices and agreeing on

a general rate or one group calling another to discuss their costs and agreeing to adjust them so that there is not a cost differential. Antitrust violations are not to be taken lightly. The penalties are potentially devastating, and, in these situations, triple damages are often imposed of whatever the difference might be from the competitive cost in regard to seemingly innocent collusion.

THE STARK ACT AND ANTI-KICKBACK STATUTE

Violations of the Stark Act and Anti-kickback Statute are actively investigated. Pursuant to the Stark Act, an ophthalmologist is prohibited from referring a Medicare patient for certain designated health services to an entity with which the ophthalmologist has a financial relationship, unless the ophthalmologist satisfies one of the safe harbor provisions contained in the Act. Under the Anti-kickback Statute, individuals and entities are subject to criminal penalties if they knowingly and willfully offer, pay, solicit, or receive bribes, kickbacks, or other benefits in an effort to induce the generation of business that is reimbursed by Medicare or other federal healthcare programs.

There are multiple safe harbors clearly spelled out in regard to comanagement. If not carefully worked out, however, some cases of comanagement in which the surgeon clearly could easily handle the postoperative care can create cause for investigation and penalties and, therefore, deserve careful scrutiny. If there is any question whatsoever, legal review is recommended, because the penalty can be severe, even including jail time.

Bundling is another area of concern in regard to the Anti-kickback Statute. Bundling occurs when an entity provides an item or service for free or for a fee that is less than the fair market value in order to induce the purchase of another item or service. Because a package price is often given in ophthalmology, even a sense of a gift or inducement to buy a product for a

decreased cost in other areas (ie, the cost of phaco equipment is added for free) can be considered a violation of the Anti-kickback Statute. A loss of licensure can occur, depending upon the severity of the claim. This problem could pertain to presbyopia-correcting IOLs if the ophthalmologist purchases a lens with bundling that might represent a significant discount on his purchase of equipment or other items. If not extremely carefully constructed, such bundling could result in an investigation and penalties with all of the concerns associated with the Anti-kickback Statute.

CONCLUSION

The OIG is clearly looking at a few specific issues in relation to presbyopia-correcting IOLs. Although ophthalmologists generally lack a legal background, we still need to recognize when we are on thin ice. If there is even a hint of concern, we should obtain legal advice. Following a sound legal opinion is an important defense should our practices ever be investigated.

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