



AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

December 29, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Attention: CMS-1403-FC

Re: Payment Policies Under the Medicare Physician Fee Schedule (MPFS) and Other Revisions to Part B for CY 2009

Dear Acting Administrator Weems:

The American Society of Cataract and Refractive Surgery (ASCRS) is a medical specialty society representing more than 9,500 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the majority of cataract procedures done annually in the United States.

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association of more than 1,100 ophthalmologists, nurses, and administrators who specialize in providing high quality ophthalmic surgical procedures performed in cost-effective outpatient environments, including ambulatory surgical centers (ASCs).

We appreciate the opportunity to offer our support and share our concerns about the 2009 MPFS Final Rule.

Physician Quality Reporting Initiative (PQRI) and Related Issues

We would first like to express our appreciation for CMS' efforts to address the significant and mounting concerns we, along with the rest of the medical community, have relayed to the agency about the PQRI program. As you are aware, we brought forward several concerns on behalf of our members related to the PQRI. In some cases carriers were processing claims with quality data codes improperly or not at all, or carriers were providing misinformation about how to report quality codes on their claims. In other cases, there were significant problems associated with the National Provider Identifier (NPI) - a key component to participating in the PQRI, since it is based on individual physician reporting. We also registered concerns regarding the inability

of members to access their feedback reports, receive their bonus payments or understand the reason for their failure to qualify for a bonus. Finally, we expressed significant concerns with CMS' plan to list those physicians who participated in the PQRI program on its web site.

While we believe that many of our members will benefit from the steps CMS has recently outlined, which aim to address some of the problems we helped identify early-on, many of which were described in CMS' recent publication on the 2007 PQRI reporting experience, we continue to have concerns with the areas CMS has not addressed. Specifically, we remain concerned with the inability of providers to receive timely feedback on their PQRI performance, the lack of informed and educated customer service representatives at the carrier level who can respond adequately and appropriately to questions and concerns about the PQRI program, and the lack of an appeals process. We are also concerned that CMS has published the names of individuals who participated in the PQRI, despite our concerns.

We understand that CMS is considering options for providing quarterly statistics about each individual measure to the medical specialty societies, but we are concerned this will not be as helpful as the agency intends it to be. Consider this; A provider is required to meet an 80% threshold on X number of measures. If the provider implements the PQRI on January 1 of the reporting year and learns in April of that year that he or she has followed a failing protocol for reporting quality data codes, the window of opportunity for correcting the problem may already be closed. As you can imagine, reaching an 80% threshold can be rather difficult, and the only other option for the provider to become a successful PQRI participant would be reporting through a registry, which may or may not be a viable option. If providers could receive immediate feedback within the first or second month of the program, they are more likely to be successful, receive a bonus incentive payment, and continue to participate in similar quality reporting initiatives.

As you know, the vast majority of our members who participated in 2007 but did not receive a bonus incentive for their efforts, immediately discontinued reporting in 2008 and do not plan to begin in 2009. They want to avoid wasting more time on an effort that provides neither a bonus incentive nor an explanation for where they went wrong and how to fix it.

Implementation of the PQRI could be likened to implementing an electronic health record or e-prescribing solution; there must be a significant effort on the front end to ensure that providers can adapt to the new program and do not become discouraged. To that end, CMS might consider identifying "super users" at the carrier and regional levels that could work with local providers to ensure they are able to successfully report. Perhaps CMS should consider tasking its carrier medical directors and carrier advisory committee representatives (CACs) with such a challenge.

We are also concerned with the lack of training CMS' carriers and Medicare Administrative Contractors have provided to its customer service representatives (CSRs) who are taking calls from our members on the PQRI. Stories about CSR's who have never even heard of the PQRI are not uncommon. You can imagine the doubt and suspicion this raises in the mind of a practice administrator or billing clerk who is attempting to confirm that quality data codes have indeed

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 Umber Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

been received and appropriately accounted for by the carrier only to find that the voice at the other end of the line has no idea what he or she is talking about.

In addition, we continue to believe that a fair appeals process is a necessary and warranted component of the PQRI program. As you know, many of our members were able to provide documentation to support their claim that they successfully reported quality data codes to CMS and met the 80% threshold. Because of the unique nature of the situations, CMS staff were willing to review most of the cases we brought forward on their behalf. Unfortunately, however, without an appeals process in place, the remaining individuals have no mechanism to dispute CMS' assertion that they failed to report successfully now or in future years. We also disagree that it would require an inordinate amount of time and effort on the part of the carriers and administrative contractors. These entities already have in place an appeal processes for claims. Because the PQRI is primarily a claims-based reporting program, we believe that CMS should be able to manage a similar process for PQRI-related appeals.

Finally, CMS has recently reported the names of eligible professionals who reported quality data under the 2007 PQRI on its web site. While we support transparency, we recommended that before any information was released publicly, a formal independent evaluation of the PQRI program's processes and an analysis and validation of the data gathered are needed to provide transparency to participants be carried out. We believe it was unwise to release data any sooner. Unfortunately, our request was not considered, and the names of participants have been published through CMS' provider directory as of December 19, 2008. Even more concerning is that important disclaimer language is not prominent on the site, but rather buried in pages that follow the list of providers who participated. We hope CMS will consider other options for making the disclaimer language more accessible. For example, CMS might consider using a "pop-up" window that requires one to review and acknowledge the disclaimer before proceeding to the list of participants. This could be carried out in a manner similar to how CMS provides disclaimer language regarding the license agreement for the American Medical Association (AMA) for Current Procedural Terminology (CPT).

We believe it is CMS' objective to have a high level of participation and satisfaction with the PQRI and related quality initiatives, therefore, any efforts that would help providers know if they are reporting correctly, and that their claims are being counted appropriately, would go a long way. In addition, if the PQRI program is truly about improving the quality of care Medicare beneficiaries receive, it seems that providing appropriate training and timely feedback would be an obvious approach to helping providers become successful PQRI participants. We ask CMS to continue its dialogue with us and the rest of the medical community, and consider the above noted options for improving the PQRI program now and in the future.

E-Prescribing

ASCRS and OOSS support incentives to assist their members with the adoption of e-prescribing technologies; however, we are concerned with the program created under MIPPA, which not only provides a limited bonus incentive for years 2009 through 2013, but will ultimately penalize physicians who do not adopt by a date certain, with some exceptions. We are also very

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 Umber Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

concerned about the mechanism by which CMS might choose to implement an e-prescribing program. As the agency is aware, the 2007 PQRI did not enjoy the success that was anticipated. Close to half the providers who reported quality data in the 2007 PQRI did not receive a bonus incentive for their efforts nor have they been able to troubleshoot where they went wrong. With the e-prescribing program being designed and implemented in a fashion similar to the PQRI, we are concerned it will produce a similar outcome and create the same level of angst that providers now face over the 2007 PQRI results.

We also understand that CMS has the authority under MIPPA to make some exceptions for providers with a hardship; however, it is not clear from the statute what qualifies as a hardship, and we are still concerned with how CMS will make this determination.

We urge CMS to issue closely monitor the e-prescribing program and continue to work with the medical community to ensure the initiative will be successful and worthwhile for our members to participate.

Independent Diagnostic Testing Facility (IDTF) Proposal

We appreciate that CMS has deferred the implementation of its IDTF proposal while it reviews public comments received on this provision. CMS originally proposed to require physician offices that provide diagnostic testing to enroll as IDTFs and comply with most of the standards now required of stand-alone testing facilities. This broad-based proposal would have included even basic tests such as ultrasound and electrocardiograms so that physicians would be required to complete a very lengthy application, on-site inspections, and proof of competency for each type of test that is performed.

As we noted in our previous comments, ultrasound is deeply integrated into the care that ophthalmologists provide patients. Our members operate the equipment themselves to make immediate patient management decisions and to guide minimally invasive diagnostics and therapeutics. Our members are thoroughly trained in the use of the technology in their discipline, and the imaging technology is safe, noninvasive, and relatively inexpensive. In fact, only an ophthalmologist has the training and expertise needed to supervise these studies. By imposing these enormous administrative burdens on ophthalmology practices, requiring them to enroll as an IDTF, will not improve quality or decrease costs.

ASCRS and OOSS certainly appreciate the value of highly trained competent individuals performing these tests, however, we continue to believe there is no evidence to support the imposition of yet another burdensome and expensive requirement with unknown benefits. We will continue to oppose any proposals that would enforce the requirements described above.

Budget Neutrality Adjustment

We are pleased that Congress addressed the budget neutrality adjustment in the fee schedule and that it will be applied to the conversion factor rather than physician work values. As you know,

ASCRS, OOSS, and the overwhelming majority of physician specialty organizations urged CMS to do this for the past two years. As we explained before, the application of a budget-neutrality work adjuster to the work RVUs is counterintuitive and halts the progress made by specialty societies, the AMA Relative Value System Update Committee (RUC), and CMS, which spent countless hours developing accurate changes to work RVUs. In addition, the application of a budget-neutrality adjuster to the work RVUs goes against CMS' longstanding policy that adjustments to RVUs to maintain budget neutrality are ineffective and cause confusion. It is for this reason CMS has been applying budget-neutrality adjustments, due to changes in the work RVUs, to the physician fee schedule conversion factor since 1998.

Physician Resource Use

We are concerned with CMS' plans for measuring physician resource use, particularly if that requires the use of one of the three major proprietary "episode grouper" software programs. First, the clinical logic behind the available programs is not publicly available, and we have significant concerns about the potential lack of transparency should the agency proceed with any of the products listed in the final rule.

Second, we are concerned that, because the episode grouper software programs use claims data to create episode groups, and because coding "rules" and practices vary between settings, there is a strong potential that CMS will not be able to develop reasonable episodes of care that fully account for a patient's health status. Some of these concerns have already been discussed with the agency during face-to-face meetings.

We would appreciate CMS' consideration of these important concerns as it moves forward with measuring physician resource use. We would be happy to have a dialogue with the agency to explain these issues in greater detail and work to find mutually agreeable solutions to addressing our concerns.

Medicare Physician Enrollment Issues

According to the final rule, CMS will reduce the retroactive billing window to 30 days from the existing 27-month timeframe. We are concerned with this significant reduction in the time allowed for retroactive billing, particularly at a time when CMS is just beginning to implement the new internet-based enrollment tool. As with any new system, it will take time to work out the bugs and, in addition to having to submit accompanying documentation since electronic signatures won't be accepted, many of our members will have to continue to file paper applications per CMS policy.

Second, physicians in many parts of the country are experiencing tremendous cash flow problems caused by ongoing problems with the transition from carriers to Medicare Administrative Contractors.

Finally, several MACs/carriers are experiencing processing delays for current 855s that are significantly in excess of CMS' own performance measures. We believe these are compelling

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 UMBER Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

reasons for CMS, at a minimum, not to impose new restrictions until these other situations are fully rectified and the PECOS system is reliable in all areas of the country. **We urge CMS to delay implementation of the reduced retroactive timeframe for billing privileges and review the need for such a drastic reduction in the billing timeframe.**

Sustainable Growth Rate (SGR)

Due to the flawed Sustainable Growth Rate (SGR) formula and the “band-aid” approach Congress again used this year to prevent the unsustainable cuts, physicians are now faced with a 21% reduction in their Medicare payments beginning January 1, 2010. The flawed formula is also slated to produce steep negative updates of more than 40% through 2017. CMS has agreed with the medical community, Congress, and policy experts that the SGR formula is unsustainable. However, since 2002 the agency has done nothing to address some of the problem areas over which it has control. Some problems have been discussed by ASCRS and OOSS in previous comments, and we outline them again below.

Removal of Physician-Administered Medicare-Covered Drugs Retroactively

We again ask CMS to use its administrative authority to remove drugs from the physician payment pool retroactive to 1996, filling the gap between actual spending and target spending, thereby, making it more likely Congress will permanently repeal the SGR.

Here are the facts:

- Physicians do not have control over the cost of drugs and biologics.
- Part B drugs are not procedures, diagnostic tests, or services.
- Part B drugs are only used in conjunction with certain procedures, diagnostic tests, and/or services.

For the 6 years, ASCRS and OOSS as well many other medical and specialty societies, members of the Medicare Payment Advisory Commission (MedPAC) and the Practicing Physicians Advisory Committee (PPAC), the Government Accountability Office (GAO), congressional committees with jurisdiction over the Medicare program, and the majority of Congress have identified the cost of physician-administered drugs as a primary factor that drives physician spending above the expenditure target. Collectively and independently, these groups have consistently recommended that CMS use its administrative authority to remove drugs from the definition of physician services back to the base year, 1996.

We continue to believe the agency has the authority to follow through with our requests. CMS is aware that making these adjustments would drastically reduce the cost of replacing the flawed SGR formula with a stable payment system, and there is overwhelming support in favor of making this necessary change. At the very least, we urge CMS to use its authority to remove drugs from the SGR pool, prospectively.

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 Umber Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780

Accurately Accounting for Changes in Law and Regulation

We continue to believe that new coverage decisions—national and local—have an impact on utilization. Most notable are coverage decisions that require certain diagnostic tests be performed in conjunction with the procedure(s) being addressed by the coverage decision. Furthermore, we understand that only coverage decisions added to the program by legislation—not by regulation—have been accounted for in the expenditure target. However, we continue to believe that CMS should include all coverage decisions—whether added to the program by statute or by the agency—when calculating the expenditure target.

In previous comments, ASCRS and OOSS used as an example the national coverage determination (NCD) on ocular photodynamic therapy (OPT) with verteporfin (Visudyne) for age-related macular degeneration (ARMD). This NCD, which was implemented in April 2004, expanded coverage for this type of therapy to beneficiaries with certain diagnoses; however, the coverage decision states that the newly expanded coverage is only allowed “provided certain criteria are met.” As a result of the coverage policy created, physicians are required to perform certain diagnostic tests to perform OPT with verteporfin.

Therefore, CMS is directly responsible for volume increases related to certain services and procedures and must adjust the SGR target accordingly.

We recognize that CMS has not solicited comments on these topics; however, we respectfully request that CMS respond to our concerns about the SGR and include a plan of action for addressing the issues noted above, which the medical community continues to raise.

ASCRS and OOSS look forward to working with CMS on the 2009 Medicare physician fee schedule. Should you have any questions or comments, please contact Emily L. Graham, RHIA, CCS-P, ASCRS Associate Director of Regulatory Affairs, at 703-591-2220 or egramham@ascrs.org, or Michael A. Romansky, OOSS Legal Counsel, at 301-332-6474 or MRomansky@OOSS.org.

Sincerely,



Bradford J. Shingleton, MD
President, ASCRS



Larry Patterson, MD
President, OOSS

AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY

4000 Legato Road • Suite 700 • Fairfax, Virginia 22033-4055 • (703) 591-2220 • Facsimile (703) 591-0614

OUTPATIENT OPHTHALMIC SURGERY SOCIETY

6564 Umber Circle • Arvada, CO 80007 • 866-892-1001 • Facsimile 303-940-7780