

September 2, 2014

Marilyn B. Tavenner, MHA, BSN, RN
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P. O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015. (CMS-1612-P)

Dear Administrator Tavenner:

The American Society of Retina Specialists (ASRS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule (CMS-1612-P), published on July 11, 2014 in the *Federal Register*, regarding the proposed policy revisions to the 2015 Medicare physician fee schedule (PFS). ASRS is the largest retinal organization in the world, representing more than 2600 members in every state, the District of Columbia, Puerto Rico, and 53 countries.

There are a number of provisions in the proposed rule that impact retina specialists and the Medicare beneficiaries they treat. ASRS offers comments in the following areas:

- Valuation and Coding of Global Service Package
- Changes in Malpractice Relative Value Units (RVUs) for Ophthalmology Services
- Reports of Payments or Other Transfers of Value to Covered Recipients under Open Payments
- Physician Quality Reporting Program (PQRS)
- Physician Value-Based Payment (VBP) Modifier Program

VALUATION AND CODING OF THE GLOBAL SERVICE PACKAGE

While ASRS supports the goal of increasing the accuracy of physician payment, **we ask CMS to not finalize its proposal to transition all 010- and 90-day global codes to 000-day global codes by 2017 and 2018, respectively.** ASRS has serious concerns that CMS' proposal would not accurately account for physician work, practice expense, and malpractice risk for services

performed within the current surgical global period. We also concur with the AMA's analysis that an upward shift in the level of post-operative E/M reporting would likely occur under CMS' proposal. The vast majority of 010- and 090-day global codes have post-operative visits that are typically coded at relatively lower levels than separately-reported E/M visits. The median established office visit in a global surgical package is a 99212, whereas the median level for separately-reported visits is a 99213. The AMA's evaluation shows that only one percent of all established patient office visits in 010- and 090-day global surgery packages have a visit level above a 99213, whereas 43 percent of all separately-reported E/M visits are reported as a 99214 or 99215.

We recommend that CMS work jointly with the RUC Relativity Assessment Workgroup to collect and review existing, objective data in order to validate bundled post-operative visits.

We do not believe that CMS' proposal adequately considers the multitude of challenges associated with its proposal, highlighted below, as well as its ability to process the more than 63 million additional claims that the AMA estimates would be filed as a result of elimination of the global period.

- Many vital and routine patient care services that are currently in global service packages have no separate coding or reimbursement. Therefore, unbundling global service packages would require separate reporting (new codes and valuation) of non-evaluation and management (E/M) post-operative physician work.
- There is a different mix of post-operative direct practice expense (PE) inputs for global period E/M services and separately-reported E/M services. These differences are warranted, and, if unbundling does occur, CMS should still account for these additional direct PE inputs for the post-operative period of surgical procedures via new and/or existing CPT/HCPCS codes.
- CMS must consider the effects of its proposal on the indirect practice expense payment, derived from the weighted average of the specialty mix that performs each service. Currently, the indirect PE related to the post-operative work for surgical services is correctly derived from the costs associated with the surgical specialties performing the service. Under the CMS proposal, this post-operative work would be inappropriately diluted due to the broad mix of specialties which perform separately reported E/M services. The unbundling of post-operative E/M visits would result in a decline in indirect PE payment for many specialties, which does not accurately reflect the actual indirect PE resources for post-operative services.
- CMS must also address, as a consequence of its proposal, the large redistribution of the professional liability insurance (PLI) payment from the primary providers of surgical procedures

to a more diverse group of providers. The PLI RVU for each service is calculated by multiplying the work RVU by the specialty risk factor of the particular specialties which perform the service. Currently, the work RVUs of the proxy E/M services contained in the global period for 010- and 090-day surgical codes are part of the PLI calculation. This is appropriate because the liability costs of a specific service should be derived from those of the performing specialties. Under CMS' proposal, the liability costs associated with the post-operative work would be removed from the primary service and would be artificially diluted by the wide mix of specialties performing all types of E/M services. Without global periods, a one-size-fits-all approach to PLI will be unsustainable and result in great disparities between the actual and realized malpractice costs for many physician specialties.

CHANGES IN MALPRACTICE RELATIVE VALUE UNITS FOR OPHTHALMOLOGY SERVICES

In the proposed rule, CMS has, as part of its five-year review, refinements to PLI RVUs. As part of that process, CMS is proposing to use any non-physicians in its PLI calculations. In doing so, ASRS asks that when CMS looks at the dominant specialty for a service, it must ensure claims reported are for the surgical portion of the procedure for which the PLI is being considered. We believe the proposed PLI RVU for ophthalmic surgeries is deflated because CMS assumes that optometry is providing the surgical portion of the procedure, which is not the case. Optometrists are involved only during the pre- or post-procedure periods. Therefore, **ASRS joins the American Academy of Ophthalmology (AAO) in asking that optometry be removed from the calculation of PLI values for ophthalmic surgery.**

While PLI RVU changes for ophthalmology is largely attributed to changes as part of the five-year review, PLI RVUs for some ophthalmology services will be further reduced due to an error CMS made in calculating the PLI RVUs for ophthalmology codes in the last five year review. **In order to mitigate these anticipated reductions, ASRS asks CMS to phase in the correction to ophthalmology PLI values through 2016.**

REPORTS OF PAYMENTS OR OTHER TRANSFERS OF VALUE TO COVERED RECIPIENTS UNDER OPEN PAYMENTS

ASRS opposes CMS' proposal to remove the current exclusion [§ 403.904(g)(1)] from the Open Payments system the reporting of payments associated with continuing education (CE). We acknowledge an unintended consequence of current regulation has been CMS' apparent endorsement or support to organizations sponsoring continuing education events. However, we believe removing the exclusion entirely and re-designating CE payments under the exclusion in §403.904(i)(1) leaves CE speakers/faculty vulnerable to reporting by manufacturers or applicable group purchasing organizations (GPOs), which could have a chilling effect on CE in this country.

Under §403.904(i)(1), indirect payments or other transfers of value are excluded from reporting where the applicable manufacturer is “unaware” of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year. This means that manufacturers who fund CE must be unaware of a speaker, who is a covered recipient, for essentially up to a year and a half after the indirect payment has been made. We believe this standard of “unaware” is wholly unrealistic because it would not be uncommon for industry to learn the identities of speakers/faculty, and potentially participants, through brochures, programs, and other publications after funds have been transferred.

CMS states in the proposed rule, **“When an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under §403.904(i)(1).”** We believe this exclusion should be made explicit under §403.904(i)(1). However, we hold the position that any standard based on the time at which a manufacturer or GPO becomes aware of a CE speaker/faculty is unreasonable and will prevent covered recipients from serving as speakers/faculty, and potentially participating, in CE programs. Clarifying that reporting for CE activities would only be triggered where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity is a necessary improvement to CMS’ proposal. However, the “before” standard does not account for the common practice of continued solicitation of industry support for a CE program after the program course and faculty have been confirmed and publicized.

Given the ramifications of deleting § 403.904(g)(1), we ask the section be maintained until CMS can arrive at an alternative solution that will provide the same level of exclusion as currently offered to CE activities under § 403.904(g)(1).

PHYSICIAN QUALITY REPORTING PROGRAM

PQRS Measures

ASRS shares CMS’ desire to ensure that program measures address performance gaps and lead to improved outcomes. However, we respectfully ask CMS for greater program predictability.

CMS is proposing, effective 2015, to change the National Quality Strategy domain for 24 measures, remove 73 measures, and modify allowable reporting mechanisms for 56 measures. These significant changes are accompanied by increased reporting requirements to avoid the 2017 PQRS payment penalty.

We share CMS' desire to gradually move away from claims reporting as the predominant reporting mechanism and toward greater use of registry and EHR reporting, especially given the continued high error rate for claims reporting. However, physicians are acutely impacted by sudden changes in PQRS measures and reporting requirements to improve program predictability. **ASRS, therefore, suggests that CMS institute a policy that allows a phase-out period when measures are to be eliminated or their reporting mechanisms significantly altered.** A transition period provides adequate time for practices to make necessary adjustments in their reporting practices, which is especially important given that physicians will increasingly rely on PQRS measure performance data in their Quality and Resource Use Reports to make practice improvements and adjustments in the context of the VBP modifier.

ASRS specifically opposes CMS' proposal to eliminate the following measures:

- NQF #87 / PQRS #14 – Age-Related Macular Degeneration (AMD): Dilated Macular Examination
- NQF #566 / PQRS #140 – AMD Counseling on Antioxidant Supplement

ASRS opposes CMS' proposal to eliminate the claims reporting option for the following measures beginning in 2015 given the continued high reliance on claims reporting by ophthalmologists:

- NQF #89 / PQRS #19 – Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care
- NQF #55 / PQRS #117 – Diabetes: Eye Exam

ASRS opposes removing claims and registry reporting for the following measure:

- NQF #88 / PQRS #18 – Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy

Furthermore, ASRS joins AAO in opposing the inclusion of the following measures:

- Adult Primary Rhegmatogeneous Retinal Detachment Reoperation Rate – *Percentage of surgeries for primary rhegmatogenous retinal detachment where the retina remains attached after only one surgery.*
- Adult Primary Rhegmatogeneous Retinal Detachment Surgery Success Rate – *Percentage of Retinal Detachment cases achieving flat retinas 6 months post-surgery.*

Our assessment is that these measures are flawed and will encourage physicians to perform retinal detachment surgeries in the hospital setting, increasing costs for both beneficiaries and CMS. In addition, we are concerned that the short evaluation timeframe specified for these measures will discourage physicians from performing less invasive and less expensive procedures such as pneumatic retinopexy because of its lower initial success rate.

ASRS does not support the addition of these measures considering their unintended consequences. ASRS members are working closely with the AAO to finalize several new quality measures to evaluate the outcome of retina procedures (including rhegmatogenous retinal detachment). These measures, unlike the proposed measures, include other important factors such as visual acuity in eyes with attached maculas preoperatively.

Finally, these measures have not been broadly tested and their inclusion in PQRS at this time conflicts with the assessment by the Measure Application Partnership that the measure is “not ready for implementation.”

PQRS 2012 Experience Report – Ophthalmologists

According to CMS’ 2012 Experience Report, the following are the top reported measures by ophthalmologists. Because retina specialists do not have a Medicare specialty designation, we have to assume that reporting patterns by retina specialists have been similar to those of general ophthalmologists.

1. PQRS #14 – AMD: Dilated Macular Examination
2. PQRS #12 – Primary Open Angle Glaucoma: Optic Nerve Evaluation
3. PQRS #117 – Diabetes: Eye Exam
4. PQRS #18 – Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy
5. PQRS #140 – AMD Counseling on Antioxidant Supplement

CMS is proposing to remove two of these top five reported measures (#14, #140) and is proposing to eliminate claims reporting for two (#117, #18).

The 2012 data also tell us that ophthalmologists still rely heavily on claims-based reporting. Of the 11,135 ophthalmologists who participated in PQRS in 2012, 8,133 reported individual measures via claims. Of those individuals who reported individual measures via claims, 5,993 received an incentive payment.

By removing the AMD measures and eliminating claims reporting for measures most likely to be reported by retina specialists, our assessment is that it will be nearly impossible for ASRS members to identify nine measures to report.

Proposed PQRS Reporting Requirements

Eligible professionals would greatly benefit from a period of PQRS program stability during which no significant changes to the program are made. Therefore, we ask CMS to publish each year, as part of the proposed rule, a multi-year timeline of anticipated PQRS changes so eligible professionals can engage in more predictable planning.

Eligible professionals participating as individuals and reporting on individual measures must report on at least nine measures covering at least three of the quality domains to avoid a 2017 payment adjustment. These two requirements are uniform across all reporting mechanisms (claims, traditional registry, electronic health record, or qualified clinical data registry).

We appreciate CMS is proposing to increase the number of measures reported by eligible professionals to better capture the picture of beneficiary care, particularly for the purpose of evaluating physician performance under the VBP modifier. However, we are concerned the increase from three to nine measures may result in a greater number of unsuccessful PQRS participants. These increased reporting requirements are proposed at the same time CMS is proposing to set the VBP modifier at -4 percent for unsuccessful PQRS participation. According to the 2012 Experience Report, 83 percent of individual eligible professionals reported using claims. Of those using claims to report individual measures, 72 percent received an incentive payment. Because the reporting threshold in 2012 was only three measures and was accompanied by a significant number of unsuccessful participants, we are concerned that a requirement of nine measures will result in an even higher PQRS failure rate, especially if the majority of PQRS participants continue to rely on claims reporting.

We ask CMS to hold PQRS requirements steady from at least the 2014 to 2015 performance years, which would include not increasing the measure reporting threshold from three to nine.

PHYSICIAN VALUE-BASED PAYMENT MODIFIER PROGRAM

Proposed Expansion of the VBP Modifier

Consistent with CMS' mandate, the proposed rule expands the application of the VBP modifier to group practices with two or more eligible professionals and to solo practitioners in CY 2017, which will be tied to CY 2015 physician performance. Using its administrative authority, CMS further proposes to expand the VBP modifier in CY 2017 to non-physician eligible professionals. Expanding the application of the VBP modifier to all eligible professionals necessitates the continued classification of groups into Category 1 as both those self-nominating to participate in the Group Practice Reporting Option (GPRO) or if 50 percent of eligible professionals in a

practice meet PQRS criteria as individual reporters. The 50 percent threshold option is important because non-physician eligible professionals may not report the same measures or use the same reporting mechanisms as physician members of a practice. Consequently, if all eligible professionals in a practice do not use the same reporting mechanism, participating as a GPRO is not an option because all eligible professionals under a GPRO must use the same reporting mechanism.

VBP Categorization of Group Practices and Solo Practitioners Based on PQRS Participation

We generally support CMS' proposed continuance of its policy to place groups of physicians, and now also non-physician eligible professionals, into one of two categories: Category 1 – Group reporters, individual reporters within a group, and solo practitioners who meet the criteria to avoid the 2017 payment adjustment; and Category 2 – Groups of eligible professionals that do not fall within Category 1.

As stated above, we support the continued policy of including in Category 1 those practices that do not self-nominate to participate in the PQRS GPRO but have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory PQRS reporting. This policy allows eligible professionals to use the full range of reporting mechanisms available.

Proposed Changes to Payment Adjustment Amounts

Category 1 Eligible Professionals

For the 2016 payment adjustment, group practices had the option to elect quality tiering. CMS is proposing for the 2017 payment adjustment that all groups and solo practitioners in Category 1 would be subject to quality tiering. **ASRS supports CMS' proposal to subject groups with 2-9 eligible professionals and solo practitioners to only upward or neutral adjustments derived under quality tiering.**

Within Category 1, CMS is increasing the payment adjustment amounts under quality tiering in the following categories: medium quality/high cost (-2%), low quality/average cost (-2%), and low quality/high cost (-4%). ASRS appreciates CMS' challenges in a budget neutral scheme. However, we object to CMS doubling the downward adjustments in Category 1. In fact, we do not understand why CMS continues to propose putting physicians and other eligible professionals who successfully participate in PQRS and get placed in Category 1 at the same risk for downward adjustments as those who did not fulfill PQRS requirements. **Given that CMS continues to make methodological refinements to the VBP modifier program and because eligible professionals in Category 1 have demonstrated a desire to improve health quality and outcomes through their successful participation in PQRS, we ask CMS to maintain for**

the 2017 payment year the current maximum two percent VBM penalty for larger group practices under quality tiering and recommend that CMS continue to hold harmless from downward adjustments practices with between 10 and 99 providers.

Category 2 Eligible Professionals

CMS is increasing the payment adjustment from -2 percent to -4 percent for eligible professionals who are not successful PQRS participants and who, therefore, get placed in Category 2. ASRS does not agree with CMS' proposal to increase the penalty to -4 percent during the first year in which the modifier will be applied to all eligible professionals and at the same time CMS is proposing to make the PQRS reporting requirements more stringent.

Even though groups of 2-9 eligible professionals and solo practitioners are not subject to downward adjustments under quality tiering, they are still at risk of a proposed -4 percent adjustment if they fail to successfully participate in PQRS. **Therefore, we ask CMS to lower the penalty in Category 2 for groups of 2-9 eligible and solo practitioners to one percent for the 2017 payment year.**

Additionally, CMS should not increase the penalty for all Category 2 eligible professionals and should instead maintain it at 2 percent.

Alternatively, or in combination, CMS should reduce the potential of a group practice or solo practitioner from being placed in Category 2 and receiving a downward adjustment by maintaining current PQRS requirements at three measures and/or by giving credit for attempts at successful PQRS participation. For example, CMS could reinstitute the administrative claims default for placing an eligible professional in Category 1 and for calculating a quality score in instances when a group practice or solo practitioner attempts to participate in PQRS but fails to successfully meet reporting requirements.

VBP Modifier Quality Measures

ASRS supports the continued alignment between PQRS and the VBP modifier. In particular, we support CMS' proposal to continue to include all of the PQRS GPRO reporting mechanisms available for the CY 2015 PQRS reporting period and all of the PQRS reporting mechanisms available to individual eligible professionals. We also support CMS' proposal to use all of the quality measures that are available to be reported under these various reporting mechanisms to calculate a group or solo practitioner's VBP modifier in 2017.

CONCLUSION

ASRS appreciates the opportunity to provide comments on the 2014 physician fee schedule proposed rule. If we may provide any additional information, please contact Jill Blim, ASRS Executive Vice President at jill.blim@asrs.org.

Sincerely,



Tarek S. Hassan, MD
President