



AMERICAN SOCIETY OF CATARACT AND REFRACTIVE SURGERY
OUTPATIENT OPHTHALMIC SURGERY SOCIETY

September 2, 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

Re: CMS-1404-P – Medicare Program; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2009 Payment Rates

Dear Acting Administrator Weems:

The Outpatient Ophthalmic Surgery Society (OOSS) is a professional medical association representing over 1000 ophthalmologists, nurses, and administrators who specialize in providing high-quality ophthalmic surgical services in cost-effective outpatient surgical environments, particularly ambulatory surgical centers (ASC).

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

On behalf of OOSS and ASCRS, we are taking this opportunity to comment on this important proposed regulation.

OVERVIEW

The nation's 5,300 ASCs are committed to providing Medicare beneficiaries with access to the highest quality surgical care while lowering their cost-sharing obligations and assisting the Medicare program in the containment of health expenditures. Studies conducted by a multitude of federal agencies (including CMS; the Government Accountability Office; the Medicare Payment Advisory Commission; the Office of the Inspector General, HHS; and the Federal Trade Commission) have lauded the work of ASCs, recognizing that surgery centers provide care at levels of quality equal to or surpassing hospital outpatient departments (HOPD), at lower cost to the program and to beneficiaries, and in a patient-friendly and convenient environment that leads to the highest levels of patient satisfaction.

Cataract surgery in the ASC is emblematic of the phenomenon of the ASC becoming the choice of physicians and beneficiaries for site of surgery. More than 2.7 million patients receive cataract surgery each year; in consultation with their ophthalmic surgeons, more than 60 percent of them select the ASC over the HOPD as their site of surgery. A study commissioned by MedPAC and undertaken by RAND Health in October, 2006, *Further Analyses of Medicare Procedures Provided in Multiple Ambulatory Settings*, concluded that with respect to all statistically significant measurements after risk adjustment, cataract patients had fewer adverse outcomes (endophthalmitis, iris prolapse, cataract fragments, and persistent corneal edema) following surgery furnished in the ASC, as compared with the HOPD. As for program savings, in 2006 alone, Medicare saves over \$400 (\$1,388 in the HOPD vs. \$973 in the ASC) each time the cataract operation is performed in an ASC rather than a hospital, translating to hundreds of millions of dollars in expenditures annually. Moreover, out-of-pocket spending by the Medicare beneficiary is lower when his care is provided in the ASC rather than the hospital. Simply stated, with respect to cataract surgery, the highest volume Medicare surgical procedure, the ASC is the predominant choice of the Medicare beneficiary because the quality of care provided is demonstrably high and the cost savings to the patient and the program are significant.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that CMS implement by January 1, 2008 a new ASC payment system. OOSS, ASCRS, and the entire ambulatory surgery community reached consensus on the appropriate contours of an equitable and rational program. In the final ASC payment regulation that became effective this year, CMS adhered to the spirit, if not the letter, of many of these principles, most importantly, that the new payment system should be modeled on the methodology and payment rates applicable to surgical services furnished in HOPDs. In reviewing the proposed 2009 payment rule, we are very concerned that the rescaler will significantly widen the gap between the ASC and HOPD payment rates in ways that are entirely unrelated to actual cost differences in the provision of care in the two settings. In the long term, this will compromise the integrity of the new system, reduce realizable program savings, thwart competition among providers of ambulatory surgical services, and inhibit transparency regarding price and quality among Medicare providers, jeopardizing beneficiary access to affordable and high quality surgical care.

In 2008, aggregate ASC payments, calculated using the budget neutrality mechanism, are 63 percent of HOPD expenditures for the same volume of services; in 2009, under the proposed rule, aggregate ASC spending will be 59 percent of HOPD. OOSS, ASCRS, and a plethora of medical specialty organizations and health care trade associations strongly support legislation (H.R. 1823 and S. 2250) that would establish ASC payment rates at 75 percent of HOPD rates. This conversion factor, which ensures a 25 percent discount to the program every time a Medicare patient selects the ASC for surgery, strikes an appropriate balance between achieving demonstrable Medicare savings and fairly compensating ASCs for these services.

Since CMS decided almost a decade ago to overhaul the ASC payment system, our organizations have been engaged in multiple discussions and exchanges of ideas and data with the agency regarding the issues presented in this and recent rulemakings. We genuinely appreciate the agency's willingness to work with us and others within the ASC and ophthalmology communities and applaud CMS for the substantial work reflected in the

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development of the new payment system. With this same spirit of cooperation and commitment to formulating a rational and equitable ASC payment system, OOSS and ASCRS offer our specific comments below.

RESCALING OF APC RELATIVE WEIGHTS

Within the rulemaking, we are most concerned about the secondary rescaling of APC relative weights. As we noted in our comments to the proposed and final 2008 ASC payment rules, OOSS and ASCRS strongly support the utilization of the same APCs and relative weights in creating a rational and coherent encompassing the services offered by both HOPDs and ASCs. We stated in our comments a year ago that:

“Under the final rule, the same weights will likely be used only in 2008, after which time the rescaling of ASC relative weights the second time will result in further divergences in weights and payments, exacerbating exactly the types of distortions that the new system was presumably intended to correct. The only legitimate basis for change in relative payments to HOPDs and ASCs should be changes in the relative costs of providing specific outpatient services. There is little basis for believing that these variations will occur, and to the extent that they do, they should be accounted for directly through adjustments to the conversion factor.”

It is important to note that APC relative weights are already rescaled once for budget neutrality under the HOPD rules, resulting in rates that are 60 percent of HOPD; Secondary rescaling, as implemented in the proposed rule, results in exactly the type of anomalies that we projected, i.e., the significant widening of the gap in payments to ASCs and HOPDs that is unrelated to the relative costs of providing such services.

With respect to secondary rescaling of APC relative weights, we strongly support the recommendations made to CMS in comments to this rulemaking by the ASC Coalition and the Ambulatory Surgery Center Association (the ASC Association). **In general, CMS should, in the final regulation, reject the rescaling of the ASC relative weights, as this further exacerbates the gap between ASC and HOPD payments and inappropriately reduces payments to ASCs.** In summary:

- *The Medicare statute does not require CMS to rescale the relative weights.* CMS was granted broad authority to establish the new payment system for ASCs based on the recommendations of the Medicare Payment Advisory Commission and the Government Accountability Office; both entities embraced the principle of revising the ASC payment system so that its relative weights and procedure classification groups are aligned with those of the HOPD system. CMS explains that rather than using the HOPD relative weights in the ASC system, it is proposing to use a secondary rescaling to achieve year-to-year budget neutrality for ASCs. Congress imposed a budget neutrality requirement on the new ASC payment system only during the inaugural implementation year of 2008; as such,

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CMS is under no legal obligation to apply secondary rescaling and should not do so when it creates significant disparities in relative payments to ASCs and hospitals that are not related to the costs incurred in providing such services.

- Secondary rescaling distorts the relativity of payments to hospitals and ASCs and has a particularly onerous impact on ophthalmic and other single-specialty ASCs.* The relative weights for surgical services performed in HOPDs are increasing – reflecting the *increase in the overall cost of performing these services* in both ASCs and HOPDs relative to other costs. Nonetheless, the proposed secondary rescaling produces a *2.47 percent decrease* in ASC reimbursement in 2009. In fact, nine of the ten highest volume ASC services have APC relative values that have increased from 2008 to 2009, signifying that the costs of furnishing these services are higher than a year ago; with secondary rescaling, all of these services would receive *reduced* payments. The relative weight for CPT 66821 (after cataract laser surgery) increased by 6.12 percent because of higher median hospital costs, yet the rescaler has the effect of reducing the actual ASC payment by 9.78 percent. With respect to CPT 66984 (cataract extraction), the highest volume Medicare surgical procedure, HOPD median costs increased the APC relative weight by 3.81 percent; with secondary rescaling, the actual ASC payment would be reduced by 1.52 percent. Based on relative weights alone, cataract facilities would have been afforded small to modest increases in payment; however, the dollars recaptured by the rescaler result in a reduction in spending of \$27 million on the same volume of services. This is particularly problematic for ophthalmic ASCs and other single-specialty facilities that treat many Medicare patients and are unable to ameliorate these cuts by changing their payer mix or accepting fewer Medicare patients.
- CMS' methodological approach to rescaling is flawed.* Even conceding that secondary rescaling might be appropriate, the agency lacks the data needed to devise a valid and appropriate calculation. The agency is proposing to use the volume of procedures furnished in 2007 as the basis for the rescaling calculation, even though 40 percent of the procedures now covered in ASCs were not eligible for coverage in the ASC until 2008. Moreover, any shifts in site-of-service that might have emanated from significant changes in payment under ASC payment reform in 2008 are not reflected in the calculation. *ASC payment rates are already subject to a multitude of payment adjustments that artificially distort relative values, including the transition adjustment and the cap on reimbursement for office-based procedures; the proposed rescaler further compromises the integrity of the relative weights and causes further divergence in payment rates that are wholly unrelated to the costs of providing surgical services.*

As noted above, Congress did not require CMS to implement budget neutrality requirements beyond 2008. The final 2008 ASC payment rule itself provides that a secondary rescaling of the relative weights will be performed only “as needed.” Far from being mandated

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or needed, rescaling threatens the viability of the new payment system by significantly eroding the relationship between the HOPD and ASC costs and payments. As such, we strongly recommend that CMS abandon the application of rescaling to the calculation of 2009 ASC payment rates.

ASC INFLATION UPDATE

As the totality of our comments reflects, OOSS and ASCRS object to the application of any mechanism that will widen the gap between ASC and HOPD payment rates, unless it captures actual differences in the costs of providing such care. During the past quarter-century, ASCs have been provided annual updates on only a sporadic basis and facilities will have received no adjustments for inflation for the period 2004-2009, notwithstanding the fact that our costs will have risen at levels that are commensurate with those of HOPDs. While we appreciate that CMS will provide annual updates commencing in 2010, we continue to strenuously object to the use of the Consumer Price Index-Urban (CPI-U) to update ASC rates while HOPDs are provided inflationary adjustments based on the Hospital Market Basket (HMB).

The CPI-U represents an unacceptable method for calculating an update for ASCs. This index measures the average change in prices over time of all goods and services purchased by households, primarily those related to food, transportation, and housing; for example, inflation in the housing sector accounts for 42 percent of the CPI's weight. The HMB percentage increase represents the increase in the cost of the mix of goods and services (based on hospital inpatient operating costs) for the period at issue over the cost of such mix of goods and services for the prior 12-month cost reporting period. The HMB, within which wages and benefits account for almost 60 percent of the weight of the index, much more accurately reflects the types of health-related goods and services that are typically consumed in the ASC than does the CPI-U. Indeed, over the past decade, year after year, the HMB has exceeded the CPI-U by an average of about one percent.

CMS has never offered any evidence for the proposition that ASCs consume fewer or different types of resources than HOPDs. Indeed, the surgical services performed by ASC are identical to those furnished by hospitals and the costs incurred by the freestanding facility to account for staffing, equipment, supplies, overhead, and administration are commensurate with those incurred by hospitals which treat the same patients. Hence, the inflationary pressures for the same services are no different and the services are influenced by the same economic pressures in a given market. As such, the higher update proposed to be awarded to the HOPD could be argued to reward its inefficiencies while penalizing the cost-conscious behaviors of the ASC.

Moreover, as with respect to the use of a secondary rescaler, the adoption of different annual update measures is also inconsistent with the agency's stated goal of aligning the HOPD and ASC payment systems. Utilizing the CPI-U to adjust ASC payment rates for inflation drives a difference in the conversion factor between the HOPD and the ASC that is wholly unrelated to the actual cost of performing procedures. In a regulatory system under which CMS is

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attempting to parallel-track payments to HOPDs and ASCs (albeit subject to a conversion factor), it makes little sense to literally build into the equation an update factor that promises to further distort payment rates for comparable services.

CMS acknowledges in its response to comments to the proposed 2008 ASC payment rule that it possesses “considerable discretion in determining an appropriate update mechanism” and that the CPI-U is mandated for update purposes only as “the default update mechanism in the absence of any other update.” We strongly believe that the HMB should be utilized to update the rates of both HOPDs and ASCs; if CMS is concerned that it lacks statutory authority to adopt the HMB as the update factor for ASCs, the agency should aggressively urge Congress to amend current statutory law to accomplish this objective.

AREA WAGE INDEX

OOSS and ASCRS strongly recommend that CMS utilize the same wage indices for both ASCs and HOPDs. As emphasized above, we believe that any differences in payments to ASCs and HOPDs should be attributable to actual differences in costs in providing services to Medicare patients. ASCs provide the same services to the same patients in their communities, and thereby directly compete for the same employees, particularly nurses and other health professionals. As such, the relationship between payments to ASCs and HOPDs should be consistent not just in the national rates, but also in each market.

CMS is proposing to establish the ASC wage index to the “pre-floor, pre-reclassified hospital wage index” using hospital cost report data from 2005. For the inpatient and outpatient hospital systems, CMS applies a number of adjustments to the wage index that address market-specific or provider-specific competition for labor. The application of different wage index values between ASCs and neighboring hospital outpatient departments can result in payment differentials in excess of 45 percent, variations that are unrelated to the differences in treating a patient in the ASC compared to the hospital. These anomalies would be ameliorated by the use of the hospital wage index and relevant adjustments for both ASCs and HOPDs.

PAYMENT FOR OFFICE-BASED SURGICAL PROCEDURES

In our comments to the proposed and final 2008 ASC payment rules, we applauded CMS for significantly expanding the ASC procedures list to include many ophthalmic surgical services that, although more frequently performed in the physician office setting, are often appropriate for conduct in the ASC setting. However, we continue to strenuously object to the agency’s decision to cap payments for these services at the lesser of the amount allowable under the conversion factor (63 percent in 2008) or the amount the physician would receive under the non-facility practice expense component of the Medicare Professional Fee Schedule. Simply stated, CMS has given with one hand and taken away with the other. This policy makes little sense and embodies the potential to force Medicare patients into the more costly HOPD, as well as compromise patient safety by providing financial incentives for the patient to be treated in the less regulated office setting. Moreover, consistent with the underlying theme of all of our comments, we reiterate that the adoption of this policy further expands the gap between the rates

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that ASCs should receive based upon the relative values assigned to APCs and the actual rates they would be afforded after rescaling and utilization of other mechanisms that arbitrarily reduce ASC expenditures.

There are many reasons why the physician might select the ASC, rather than the office operatory or treatment room, for the conduct of a particular service. First, the patient's clinical condition, including his age, size, comorbidities, prior operative experience might dictate that the ASC is the appropriate environment for surgery. Second, there are considerable variations in the ways in which physician offices are equipped and staffed. Third, the training, skills, and experience of the surgeon may warrant the choice of one setting over the other. Fourth, state certificate of need, ASC licensure, or professional scope of practice regulations, as well as the physician's professional or facility malpractice coverage, might impact upon the choice for site of surgery. All of these considerations might legitimately impact upon the selection of the ASC for performance of the surgical procedure.

CMS has presented no evidence that coverage of office-based services in the ASC will lead to overutilization. It is true that paying for these services at the full ASC rates might lead to higher Medicare costs, but only if more procedures migrate from office to ASC than from the HOPD to the ASC; this phenomenon is difficult to predict. Nevertheless, Medicare expenditures will definitely increase by orders of magnitude if these office-type services migrate, by virtue of the caps on ASC payments, from the physician's office or ASC to the HOPD setting, where reimbursement rates exceed ASC rates by at least 35-37 percent under the new payment system in 2008 and by perhaps as much as 41 percent in 2009. The physician, in consultation with his patient, is professionally, legally, and ethically obligated to make the clinical decision as to whether the hospital, ASC, or office is the appropriate operative environment. The Medicare program should not provide, inadvertently or otherwise, reimbursement incentives which might impact upon these decisions.

OOSS and ASCRS strongly recommend that CMS reverse its policy of designating procedures as "office-based" and subjecting them to an arbitrary payment limitation. These services should be subject to the same payment methodology as all other covered procedures. If CMS remains insistent upon the continued application of the payment cap on office-based procedures, the agency should provide more flexibility in designating a service as "office-based":

- In its comments, the ASC Coalition has presented data that compellingly demonstrates that there is significant state-level variation in site of service. For example, HCPCS code 66821 (after cataract laser surgery), the sixth highest volume procedure performed in Medicare ASCs, was performed in 2006 in physician offices 41 percent of the time in Minnesota, 18 percent in Virginia, and 2 percent in Nevada. Therefore, reliance on national averages provides for questionable conclusions as to where surgery is typically performed.

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- Second, a procedure should not be subject to the office surgery cap until it has met the higher threshold for multiple years.
- Third, in order to maintain the strongest linkage to the HOPD relative weights, CMS should significantly limit the number of procedures subject to the cap. As more services are designated as office-based, the linkage between the ASC and HOPD rate-setting methodology will be further eroded, injecting the ASC system with unpredictable inflation updates from the Medicare physician fee schedule (because of varying schedules and methodologies for calculating physician payments) and distorting relative value weight scaling based upon changes in the median cost of hospital outpatient procedures.
- Fourth, the agency should address this complex issue of basing payment for many ASC services on the Medicare physician fee schedule in a future rulemaking. As we have stated repeatedly, the linkage of payment to HOPD relative weights is the best proxy for relative costs and should be maintained except where the agency determines that adjustments are appropriate to account for differences in actual costs.

PAYMENT FOR IMPLANTABLE DEVICES UNDER TRANSITION RULES

As noted in the section above, OOSS and ASCRS are pleased that CMS has incorporated within the final ASC rule special provisions to augment payment for device-intensive procedures. Similar treatment should be afforded to procedures whose devices may not be so expensive as to qualify for device-intensive status, but for which the application of a four-year transition may preclude performance in the ASC. Under current rules, ASCs are paid a facility fee for a service and a separate payment under the DMEPOS fee schedule for an implant. Under the final 2008 ASC payment regulation, these services and items are bundled and paid on the basis of the discounted (in 2008, 37 percent) rate; however, because the rates are phased in over a four-year transition period, with only 25 percent of the final rate in the first year (50 percent in the second year *et seq.*), the cost of the device cannot be viably accommodated within the ASC facility fee in the early years.

In ophthalmology, the glaucoma procedure, 66180 (aqueous shunt to extraocular reservoir), is performed when medical treatment for the glaucoma patient is no longer efficacious and the standard trabeculectomy may not be indicated or has failed. For these patients, it is necessary to insert an aqueous shunt to relieve intraocular pressure. Under the prior payment system, the aqueous shunt device was billed separately from the ASC's facility fee; in CY 2007, for example, the ASC was reimbursed \$717 for the facility fee and approximately \$560 for the implanted device, or \$1,267. Under the new rule, effective January 1, 2008, the HOPD currently receives \$1,624; however, because of the transition, the ASC is reimbursed only \$940, a reduction of \$326 from the 2007 level. Even under the proposed 2009 rule, with higher payment due to the second year of the transition, payment remains substantially lower than in 2007. Many of our members have reported that it is financially impracticable for the surgeon to provide the service in the ASC, even though the procedure has been furnished safely and effectively in these facilities for years. Similarly, the assignment of two new Category III CPT codes, 0191T and

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0192T, that utilize an implanted glaucoma drainage device akin to an aqueous shunt, to APC-234 has created an incentive to move these cases from the ASC to the HOPD setting because the payment rate is inadequate to cover the incidental prosthetic device.

Similar problems occur with respect to the application of the transition rules to payment for several ocular plastic implant services, including 65105 (enucleation of eye; with implant, muscles attached to implant); 65140 (insertion of ocular implant secondary; after enucleation, muscles attached to implant); 65155 (reinsertion of ocular implant; with use of foreign material for reinforcement); and 67912 (correction of lagophthalmos, with implantation of upper eyelid lid load). Likewise, the rule bundles payment for 65780 (amniotic membrane transplant) with the code assigned to the amniotic membrane tissue at levels that threaten the viability of the service within the ASC.

OOSS and ASCRS believe that CMS should modify the final 2008 Medicare ASC rule to ensure the continued availability to Medicare beneficiaries of services that incorporate costly medical devices or tissue and that have historically been safely and effectively furnished in the ASC environment. This can be accomplished by either paying the ASC the fully transitioned ASC payment in 2009-2011, or by including the 2007 device payment amount in the transition year payment calculations.

UNLISTED CODES

Another anomaly in CMS' effort to align the ASC and HOPD payment systems is the treatment of procedures for which there is not an appropriate CPT code. In some ASCs, surgeons utilize innovative techniques or new technologies to perform a procedure; this can mean that the service is not described by a particular CPT code. These services are reimbursed in the HOPD, but are not eligible for payment in the ASC. In the proposed 2008 ASC payment rule, CMS states that, without knowledge of the procedure's code, it cannot determine whether the procedure performed would have been excluded from the ASC payment under the rule's safety criteria. However, although an unlisted code doesn't allow the reporting of specific procedures, it does allow for reporting of the anatomic region of the service which could provide the basis for a determination about the safety of the procedure in the ASC.

With knowledge of the anatomic location, CMS can and should apply the safety criteria to the entire spectrum of services reportable by the unlisted code. Under such an analysis, the agency would determine that no procedure on the ocular muscle would compromise patient safety, and that, therefore, any service encompassed by 67399, Unlisted procedure, ocular muscle, meets the safety criteria utilized to evaluate services furnished in the HOPD and should be reimbursed in the ASC. The same analysis would result in the conclusion that services encompassed by 67299, Unlisted procedure, posterior segment of the eye, should be covered in the ASC.

In addition to the CPT manual, CMS' construction of the APCs provides a means for identifying unlisted procedures that can be safely performed in an ASC. For example, with respect to APC 032, Level I Anterior Segment Eye Procedures, the grouper was constructed by

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bringing together services that were homogeneous in terms of clinical characteristics and resource consumption. Most of the dozen procedures in APC 032 are on the ASC procedures list while the two that aren't have been designated as office-based, meaning that they are typically performed in a physician office; an unlisted code in this APC would be appropriate to report a procedure for which an appropriate CPT is not available. There are numerous other codes for Unlisted Procedures (66999, 67299, 67399, 67599, 67999, 68399, and 68899) that encompass services that meet any rational safety criteria and should be eligible for reimbursement in the ASC.

It is imperative that CMS evaluate for safety services billed under unlisted codes under similar criteria for both hospitals and ASCs.

TRANSPARENCY IN ASC PROCEDURES LIST EXCLUSIONS

With respect to ophthalmology, we are pleased that, in the 2008 ASC payment rule, virtually all ophthalmic surgical procedures have been included on the ASC list. However, we share the concerns raised by colleague ASC and medical associations that many procedures that are appropriate for conduct in the ASC continue to be excluded from the list, and, of paramount concern, that the agency provides inadequate rationale for why such services cannot be performed and paid for in the ASC. CMS should expand the reason codes to identify which specific safety/overnight standards are being relied upon to exclude a procedure, thereby providing the medical and ASC communities with meaningful opportunity to provide input to the agency.

We also note that the proposed 2009 ASC payment rule removes two codes (21386, open treatment of orbital floor blowout fracture; periorbital approach; and, 21387, open treatment of orbital floor blowout fracture; combined approach) from the inpatient-only list, yet has not added these services to the ASC procedures list. Services excluded from the inpatient-only list and eligible for payment in the HOPD should be presumed to be appropriate for conduct in the ASC unless CMS proffers evidence to the contrary of a legitimate concern for patient safety.

ASC REPRESENTATION ON APC PANEL

OOSS and ASCRS have for years advocated that the HOPD and ASC payment systems be aligned in virtually every respect and are pleased that the new system is moving in that direction. As such, the ASC industry should have a meaningful voice in all relevant deliberations with respect to issues of APC group assignments, payment weights, inpatient-only list, and standards for coverage of procedures. To this end, we believe that CMS should appoint a designated ASC industry representative to the Advisory Panel on Ambulatory Payment Classification Groups.

Thank you for providing our organizations with the opportunity to present our comments on the rule. Should you have any questions, please do not hesitate to contact our Washington

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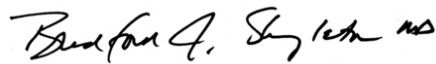
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Sincerely,



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Larry Patterson, MD
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