ASCRS 2015
Legislative Priorities
Medicare Physician Payment Reform

Background:
For more than a decade, Congress has been enacting short-term fixes to the flawed Sustainable Growth Rate (SGR) formula that have exacerbated the cost of repeal and future reductions. However, after the Congressional Budget Office (CBO) drastically reduced the cost to repeal (the latest estimate of $119 billion is far below the 2012 estimate of $300 billion), Congress took advantage of the lower cost and committees with jurisdiction over the issue began developing and passed bipartisan/bicameral legislation to repeal and replace the SGR. ASCRS has been supportive of efforts to repeal the flawed SGR, and has worked with legislators to ensure that a reformed Medicare physician payment system would maintain access to specialty care and adequately compensate physicians for their services.

In the 113th Congress, ASCRS supported the SGR Repeal and Medicare Provider Payment Modernization Act (H.R. 4015/S.2000), the bipartisan, bicameral SGR repeal and replacement legislation. The bill represented a compromise between the Senate Finance, House Ways and Means, and House Energy and Commerce committees and replaced the SGR with a 0.5% update to Medicare physician payments for five years and retained fee-for-service. In addition, it consolidated and removed the penalties associated with the Physician Quality Reporting System (PQRS), EHR/meaningful Use and the Value-Based Payment modifier to create a new Merit-Based Incentive Payment System (MIPS) that is not budget-neutral and establishes clear quality-improvement thresholds achievable by all physicians.

ASCRS worked with the medical community throughout 2014 to see this legislation enacted, but was unsuccessful. The House passed the bill in March of 2014—ahead of the scheduled 24% cut to Medicare physician payments from the SGR due to take affect April 1, 2014—but off-set its cost with a delay of the individual mandate. This partisan move was not supported in the Democratic-controlled Senate, whose leaders also failed to identify a pay-for that would be acceptable to the Republican-controlled House. Ultimately, no action was taken in the Senate on the full repeal, leading Congress to pass another one-year “patch” to the SGR through March 31, 2015. Since there were no looming end-of-year cuts in 2014, Congress focused on other issues and did not complete action on SGR repeal and replacement legislation before adjourning in December 2014.

Key Priorities for ASCRS in the 114th Congress:

ASCRS will continue to work with the medical community to support bipartisan, bicameral SGR repeal and replacement legislation. Congress has only until April 1, 2015 to act and prevent a 21.2% cut to Medicare physician payments due to the SGR. ASCRS will work to ensure that new SGR repeal and replacement legislation is introduced as soon as possible. Whether the bill will retain the same policy as H.R. 4015/S. 2000 or be slightly amended, is unclear. At a minimum, any repeal and replacement bill must be based on the following principles:
Ensure that all physicians receive adequate reimbursement. Medicare physician pay is well below market-value and has not kept pace with inflation.

Recognize reasonable inflationary medical costs.

Maintain a fee-for-service option. As other payment systems are explored in the Medicare system, it is important to maintain a fee-for-service option, as this may work best for some physicians and their patients, especially those with serious illness or in underserved areas where provider choice is already limited.

Allow Medicare beneficiaries' access to the physician of their choice. Patients and physicians should be able to contract freely, in writing, for Medicare covered services without having to lose their Medicare benefits.

Focus on performance, not penalties. We strongly support encouraging quality performance throughout the healthcare system. We urge Congress to structure quality payments in a positive, not punitive, nature; allow for the development of physician-led and clinically-relevant quality measures, and that all physicians have the opportunity to achieve performance goals.

Provide an appropriate timetable and required investment for reforms. New payment systems need appropriate time for proper implementation, as well as investment in key infrastructure. Therefore, ASCRS urges Congress to focus on ensuring that beneficiaries can maintain access to current healthcare options as new payment models are being tested.

**The Bottom Line:**
Medicare reimbursement rates are already well below market value and the SGR would continue to reduce them. The SGR needs to be repealed and replaced with a stable mechanism for updating Medicare fees to ensure beneficiaries have access to high-quality care and to allow Medicare and the healthcare system to move forward with important system delivery reform. In addition, it is imperative that Congress initiate a clearly defined transition period to implement a new payment system that will include statutory updates to physicians and keep up with rising practice costs, while new payment models are tested.
Additional Medicare Physician Payment Options: Private Contracting

ASCRS supports a patient’s right to obtain medical services from the physician of his or her choice by adopting additional Medicare payment options in conjunction with a new payment system. Under the current system, physicians must opt-out of Medicare for two years if they enter into a private contract with a patient. At the beginning of the 113th Congress the following bills were introduced in the House and Senate and are strongly supported by ASCRS:

- H.R. 1310, the Medicare Patient Empowerment Act, introduced by Representative Tom Price, MD (R-GA). This legislation had 24 co-sponsors.
- S. 236 the Medicare Patient Empowerment Act, introduced by Senator Lisa Murkowski (R-AK) with three original co-sponsors, all physicians: Sen. Tom Coburn, MD (R-OK), Sen. John Barrasso, MD (R-WY), and Sen. Rand Paul, MD (R-KY). In addition, Sen. James Inhofe (R-OK) and Sen. Roger Wicker (R-MS) also a co-sponsored.

This legislation would allow physicians and patients to contract freely on a case-by-case basis, without penalty, for Medicare services. Medicare beneficiaries will still be able to use their benefits, and physicians will be allowed to bill the patient for all amounts not covered by Medicare without being forced to opt out of Medicare for two years.

Specifically, private contracting legislation as introduced in the 113th Congress would:

- Ensure that physicians will not have to opt out of Medicare for two years;
- Create a payment option for patients and physicians to contract freely on a case-by-case basis, without penalty, for fee-for-service services, while allowing Medicare beneficiaries to use their Medicare benefits and allowing physicians to bill the patient for all amounts not covered by Medicare; and
- Provide patients with more choices of physicians, increase the number of physicians who will continue to accept Medicare patients, and help preserve the Medicare program.

Status:

Neither the House nor Senate took action on this legislation in the 113th Congress. ASCRS will continue to work with the medical community to ensure that this legislation is re-introduced in the 114th Congress and work to build support for it.
Repeal of the Independent Payment Advisory Board (IPAB)

Background:

One of the provisions included in the Patient Protection and Affordable Care Act (PPACA) was the creation of the Independent Payment Advisory Board (IPAB.) The board is made up of 15 unelected, unaccountable members appointed by the President and is required to make recommendations to Congress on how to lower costs to the Medicare program and Medicare physician payment policies. When Medicare growth exceeds the given target, the IPAB must develop a proposal to reduce Medicare spending without causing a reduction in patient benefits. This effectively means IPAB’s focus will be on reductions to physician reimbursements. The creation of IPAB will cause myriad problems, ranging from deficiencies in patient care to sufficiently lower provider reimbursement rates.

ASCRS opposes IPAB and therefore supports legislation to repeal the IPAB.

113th Congress IPAB repeal legislation:

- H.R. 351, Protecting Seniors’ Access to Medicare Act, introduced by Representatives Philip Roe, MD (R-TN) and Allyson Schwartz, (D-PA). This legislation had 227 co-sponsors—more than a majority of the House.
- S. 351, Protecting Senior’s Access to Medicare Act, introduced by Senator John Cornyn (R-TX). This legislation had 36 co-sponsors.

Status:

IPAB Repeal has strong bipartisan support in Congress and is a top priority for ASCRS and the medical community. While there was no action in the 113th Congress on this legislation, there is an opportunity to pass this legislation in the 114th Congress as part of bipartisan efforts to improve PPACA. We will again work with the medical community to ensure this legislation is introduced in 2015 and to help build support for it.
ASCRS has long supported efforts to improve access to new drugs and devices, maintaining that the current Food and Drug Administration (FDA) approval process is outdated and overly onerous. Over the last several years, ASCRS has been actively involved in several key issues including: 510(k) premarket review process reform, de novo process simplification, off-label use, medical device tax repeal, and increasing focus on improving regulatory predictability necessary for innovation.

ASCRS continues to urge Congress to be vigilant about any measures that would inappropriately increase the regulatory burden for medical device innovation, hurt America’s competitive advantage, and delay or deny appropriate care for patients. Therefore, we continue to encourage the passage of much-needed reforms that will address the delays in the approval of new devices and drugs.

**21st Century Cures Initiative**

In 2014, the House Energy and Commerce (E&C) Committee created a new, bipartisan initiative—21st Century Cures—aimed at identifying ways that Congress might bolster American medical innovation—including speeding access to new drugs and devices. The initiative, led by full committee Chairman Fred Upton (R-MI) and Rep. Diana DeGette (D-CO), is a comprehensive effort to investigate the current system of federally-supported research, drug development, clinical trials, available capital and patient experience to determine where Congress can most effectively make legislative changes or direct funding. Throughout 2014, the committee held a series of roundtables and hearings exploring different aspects of the issue and met with stakeholder groups—including ASCRS—to provide input.

Chairman Upton has announced plans to release draft legislation early in 2015 with the intention of House passage by late spring. Incoming Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) has indicated his support for this initiative as well.

ASCRS will continue to monitor and provide input when draft legislation is presented.

**Medical Device Tax**

Enacted as part of the Affordable Care Act (ACA) in 2010, the medical device tax is a 2.3% excise tax that will be levied on the total revenues of a company, regardless of whether a company generates a profit. The tax, which went into effect on Jan. 1, 2013, is on the sale of certain medical devices by the manufacturer, producer, or importer of the device. The medical device excise tax does not apply to sales of items such as eyeglasses and contact lenses. The vast majority of innovation from the medical device industry comes from smaller manufacturers.

ASCRS has opposed the medical device tax from the beginning as it could adversely affect both medical device jobs and innovation in the medical device industry and because the vast majority of innovation from the medical device industry comes from smaller manufacturers. ASCRS, in conjunction with other
medical societies, continues to work with elected officials on the bipartisan proposals to eliminate the medical device tax to ensure that patient care, innovation and job creation continue to thrive. It is likely that the repeal will be taken up early in the new 114th Congress in 2015, since Republicans will control both the House and Senate and have indicated their intention to enact changes to the ACA.
Transition from 10- and 90-Day Global Codes to 0-Day Codes

The Centers for Medicare and Medicaid Services (CMS) finalized a policy in the 2015 Medicare Physician Fee Schedule (MPFS) final rule that will transition all 10- and 90-day global codes to 0-day codes in 2017 and 2018. This proposal will affect more than 4,200 in the MPFS.

Each 10- or 90-day global code encompasses all the pre-, intra- and post-operative services involved with a procedure. ASCRS is working with the AMA and the surgical coalition to get this planned transition rescinded.

First, CMS has not yet developed a methodology for making the transition to 0-day codes, even though CMS must begin to transition these codes no later than February 2016. CMS also noted in the 2015 MPFS rule that they do not have accurate data with which to remove the practice expense and post-operative visit codes from the 10 and 90 day bundles, which will make it very difficult to effectively implement this proposal.

In addition, ASCRS noted in our comments to CMS that using a reverse building block method to systematically convert all 10 and 90-day global codes to 0-day global codes by backing out the bundled E/M services would be inappropriate and methodologically unsound. There are a number of post-operative services included in the 10 and 90-day global codes that cannot be reimbursed for using the currently separately billable E/M codes, such as dressing changes or local incision care, increasing the difficulty CMS will have with finding the practice expense data within these global packages.

Furthermore, CMS has suggested that they will most likely create new postoperative visit codes, which will be reimbursed at a lesser amount than the current primary care E/M codes. Therefore, ASCRS and other surgical societies are also extremely concerned about how this will affect the reimbursement for these 10- and 90-day global procedures.

This proposal will also negatively affect Medicare beneficiaries, as they will have to pay separate co-payments for the surgical procedure and each post-operative appointment, as opposed to one co-payment amount for all services and visits included in the cataract surgery 90-day bundle for example. In addition, this may also deter beneficiaries from attending their medically necessary post-operative appointments due to the added cost.

In addition to our comments on the proposed rule opposing this change, ASCRS joined the AMA and surgical groups in a letter to CMS voicing our opposition to this proposal. After the policy was finalized in the 2015 MPFS rule, ASCRS signed onto a second letter with the AMA and other surgical groups to the Congressional leadership urging Congress to rescind the elimination of 10 and 90 day globals, or, at a minimum, stop CMS from implementing the transition of codes until Congress has been provided with a methodology endorsed and tested by the surgical community, whose procedures will be affected.
In response to the advocacy from ASCRS and our coalition partners, House and Senate appropriations negotiators included language in the report of the Consolidated and Further Continuing Appropriations Act of 2015 (H.R. 83)—also referred to as the “Cromnibus”—that instructs CMS to study this proposal further and develop methodology for its undertaking. The report instructs CMS to “ensure no negative impact on patient care, patient access, and [that] undue administrative burdens are not placed on providers and CMS.” ASCRS and the specialty medical community will work to ensure that Congress’ intentions are followed in the development of the methodology and will continue to advocate for the elimination of the policy entirely.
Accountable Care Organizations (ACOs)

ACOs are part of a three-year Medicare Shared Savings Program mandated in the Patient Protection and Affordable Care Act (PPACA). The ACO, designed to lower total overall healthcare-associated expenditures while improving quality of care, is an entity operated by a group of physicians or hospitals and physicians that would be paid to manage and coordinate the care of a defined population of Medicare fee-for-service beneficiaries.

On October 20, 2011, CMS released the final rule for the development and implementation of ACOs. The ACO proposed rule was released in March and received considerable criticism from the vast majority of stakeholders and professional physician organizations, including ASCRS. In response to roughly 1,300 comments submitted, CMS made several major changes to the originally proposed program. The final rule established two new voluntary initiatives to encourage increased participation in and adoption of the ACO: the Medicare Shared Savings Program and the Advance Payment Model.

Medicare Shared Savings Program
Under the Medicare Shared Savings Program, providers enter into an agreement with Medicare to take responsibility for improving quality and coordination of care for a group of at least 5,000 beneficiaries for three years (ACOs will be told upfront which Medicare beneficiaries are likely to be part of their system), while lowering costs, in return for a share of the savings. In order to obtain shared savings in the first performance year, providers must fully and accurately report across four domains of quality: quality standards on patient experience; care coordination and patient safety; preventive health; and at-risk populations. The second and third years will be based on how they perform in reporting on 33 quality measures (reduced from 65 in the proposed rule). Under the final rule, participating ACOs will have the choice of two “tracks” with regard to risk, Track 1 participants will only share savings, not losses. The final rule stipulates that after the initial agreement period, if an ACO voluntarily continues to participate, it must participate in Track 2, which has a higher sharing rate but also has downside risk.

Advance Payment Model
The Advance Payment Model tests whether pre-paying a portion of future shared savings will increase participation of physician-owned and rural ACOs and improve care for beneficiaries and generate Medicare savings more quickly. The advance payments would be recovered from any future shared savings achieved by the team of providers. This model is open only to participating physician-owned organizations, critical access hospitals, and rural providers.

Participation/Exclusivity
Although the final ACO rule was widely interpreted as allowing non-primary care physicians to practice in multiple ACOs, CMS applied exclusivity more broadly than it had indicated in the final rule and precluded any practice that performs and bills evaluation and management services from full-fledged
participation in more than one ACO—regardless of specialty. ASCRS/ASOA was the first organization to identify this issue, and subsequently organized a coalition with the AMA to bring the issue to CMS and MedPAC and advocate for its resolution.

**Successful ASCRS/ASOA Advocacy**

On Monday, December 1, 2014, CMS released a proposed rule on Medicare Share Savings Program ACOs, which will allow ophthalmologists to participate as full-fledged participants in more than one ACO. In this rule, CMS proposes to exclude services provided by certain specialties, including ophthalmology, from the beneficiary assignment process, and thus exclude these specialties from being limited to full participation in one ACO.

The proposed rule will also allow ACOs participating in Track 1 (shared savings but not shared losses) to continue the program after their initial 3-year agreement, but at a lower sharing rate than the previous agreement period. CMS also proposes a Track 3 for ACOs in this proposed rule that will include a prospective assignment methodology and a higher rate of shared savings. This new track differs from Track 1 and Track 2 assignment methodology, which includes a preliminary prospective assignment with retrospective reconciliation.

**ASCRS will support this proposed rule in our comments to CMS and will continue to keep members updated when a final rule is released.**
Drug Compounding

ASCRS supports efforts to ensure the safety and sterility of compounded drugs. H.R. 3204 Drug Quality and Security Act (P.L. 113-54), enacted in November 2013, seeks to improve safety of compounded drugs. The Drug Quality and Security Act represents a compromise between the Senate Health, Education, Labor and Pensions (HELP) and House Energy and Commerce Committees. The bill creates a new category of pharmacies—outsourcing facilities—that would voluntarily submit to stricter FDA oversight.

H.R. 3204 incorporated some of the provisions advocated by ASCRS and the medical community throughout the year as the legislation was being developed, such as eliminating a requirement for national patient-specific prescriptions for all compounded drugs, including those made from bulk substances, and the opportunity to review the Food and Drug Administration’s (FDA) recommendations before certain drugs are placed on a “do not compound” list. The bill’s sponsors intend for traditional compounding for patient-specific prescriptions and limited office use to continue to operate under current state law. As a result of the efforts of ASCRS and the ophthalmic community, key senators including Senators Rand Paul (R-KY) and Tom Coburn (R-OK) and the sponsors of the bill, Senators Lamar Alexander (R-TN) and Tom Harkin (D-IA) submitted congressional statements for the record stating that the bill’s intent was not to regulate office use or limit repackaging.

However, ASCRS has concerns with how FDA is interpreting this new law. Most importantly for ophthalmology, the bill does not include repackaging or office use in the compounding definition and leaves it to the FDA to determine how repackaged drugs, such as Avastin, will be regulated.

While FDA has released final guidance for 503A traditional pharmacies, the guidance is confusing and inadequate on the office use of compounded and repackaged products. FDA appears to be requiring that all 503A traditional pharmacies receive a patient-specific prescription for all compounded drugs.

ASCRS and the medical community are still awaiting guidance for 503B outsourcing facilities. Outsourcing facilities can qualify from exemptions from the FDA approval requirements and labeling requirements by complying with more stringent requirements, such as the Current Good Manufacturing Practices (CGMP), inspections from FDA, and increased adverse event reporting. ASCRS has alerted the FDA that these perceived limitations on office use have left many physicians without access to necessary compounded drugs, and urged the agency to provide additional guidance on both 503A traditional compounding facilities and 503B outsourcing facilities. We will continue to update our members as additional information becomes available.