



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

ASCRS 2013

Legislative

Priorities



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Medicare Physician Payment Reform and Alternative Payment Systems

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, due to slower growth in Medicare spending, the Congressional Budget Office (CBO) released a new cost estimate in early 2013 that pegged the cost of repeal at \$138 billion, down from a previous estimate of nearly \$300 billion. On January 2, 2013, as part of the so-called “fiscal cliff” deal, Congress enacted a short-term patch until December 31, 2013, to prevent the scheduled 26.5% cut from going into effect.

Despite the current temporary fix to the SGR, the fiscal cliff deal did not reverse the spending cuts—known as sequestration—that were part of the original terms of the Budget Control Act of 2011 that created the fiscal cliff. Due to sequestration effective April 1, 2013 physicians received a 2% cut to Medicare reimbursements for fee-for service, ambulatory surgery centers, durable medical equipment, and payments from the Electronic Health Records incentive program. Without a full repeal of the SGR, physicians will face another drastic cut on January 1, 2014.

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 The SGR needs to be repealed and replaced with a stable mechanism for updating Medicare fees to ensure Medicare beneficiary access to high-quality care and to allow Medicare and the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. Physician payment reform should recognize reasonable inflationary cost increases that lead to fair reimbursement for the services provided to Medicare beneficiaries.

Repeal Proposals:

There is broad, bipartisan support for repealing the SGR. The new, much lower CBO score has initiated new efforts to find a permanent alternative to the SGR. The House Energy and Commerce and the House Ways and Means Committees released a framework to address the SGR and reform the payment system. ASCRS has been called upon by the committees to provide input on their proposal. ASCRS has provided comments on the framework and will continue to work with the committees as they develop legislation. We will push for passage of SGR repeal legislation.

Key Points:

- **Ensure that all physicians receive adequate reimbursement.** Physician shortages are looming in many specialties, not just primary care, and any payment differentials will further exacerbate significant shortages of specialty physicians.
- **Recognize reasonable inflationary medical costs,** such as the Medicare Economic Index (MEI).
- **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. However, we strongly urge Congress to structure quality payments in a positive, not punitive, nature.
- **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 that the Congress should focus on ensuring that beneficiaries can maintain access to current healthcare options as new payment models are being tested.



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

Repeal of 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 the following bills that repeal the IPAB:

- H.R. 351, Protecting Seniors' Access to Medicare Act, introduced by Representatives Philip Roe, MD (R-TN) and Allyson Schwartz, (D-PA). This legislation currently has 146 co-sponsors.
- S. 351, Protecting Senior's Access to Medicare Act, introduced by Senator John Cornyn (R-TX). This legislation currently has 31 co-sponsors.

Status:

Repeal of IPAB passed the House of Representatives in the 112th Congress, but was not considered by the Senate. ASCRS and the Alliance of Specialty Medicine worked with the previous sponsors to get the legislation re-introduced in the 113th Congress and the coalition will continue to advocate for its passage.



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

Additional Medicare Physician Payment Options: Private Contracting

ASCRS supports a patient's right to obtain medical services from the physician of his/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 currently has five co-sponsors.
- S. 236 the Medicare Patient Empowerment Act (S. 1042), 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).

Both bills will allow physicians and patients to freely contract 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.

H.R. 1310/S. 236 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.



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

Quality Improvement Initiatives

ASCRS is actively engaged in quality improvement and supports innovative efforts aimed at improving the value and effectiveness of healthcare for all Americans.

ASCRS is continuously involved in the process of developing evidence-based and clinically relevant quality measures; advocating for the appropriate use of quality data that physicians can easily and properly report; the ability of physicians to verify the data that is used in developing a physician rating under a quality program; as well as physician appeal rights with regard to various aspects of the program. In collaboration with the American Academy of Ophthalmology (AAO), ASCRS established a joint data registry with Outcome, offering a CMS-qualified comprehensive data collection and management tool for Physician Quality Reporting System (PQRS) and e-prescribing (eRx) measure submission.

ASCRS worked diligently with the Alliance and the AMA for modifications to the eRx program structure, which now includes additional exemption categories and extended reporting timelines so that physicians are not arbitrarily penalized for failing to meet the requirements of the eRx program.

We also coordinated with several other medical specialty societies in advocating for improvements to the PQRS in the development of more innovative and outcome-oriented measures - resulting in the addition of the Cataract Measure Group, which requires reporting on only 20 patients in order to meet the incentive requirement. In addition, ASCRS provides input to the AAO clinical registry that is under development.

ASCRS continues to support positive incentives that assist specialty physicians with piloting, and eventually adopting, new workflows and technologies that will enable them to provide the highest quality and most appropriate care for patients. We continue to oppose financial penalties and unattainable deadlines that do not promote, but impede, the ability to improve quality. **ASCRS believes that physician quality reporting should remain a voluntary, non-punitive process.**

Beginning in 2015, CMS will impose a 1% payment reduction under the Value Based Modifier (VBM) program for groups with 100 or more eligible providers that do not participate in PQRS in 2013. ASCRS is opposed to the VBM and concerned about the statutory requirement to apply the modifier to all physicians by 2017 and the impact this may have on specialty practices.

ASCRS remains opposed to the budget-neutral, value-based payment modifier and continues to urge CMS to delay implementation prior to thorough vetting of measures and risk adjustment methodologies.

ASCRS maintains consistent representation at important meetings such as at Physician Consortium for Performance Improvement (PCPI), National Quality Forum (NQF), Quality Alliance Steering Committee (QASC), Surgical Quality Alliance (SQA), AQA Alliance (formally the Ambulatory Care Quality Alliance), Agency for Health Care Research and Quality (AHRQ), National Committee for Quality Assurance (NCQA), and the Institute on Medicine (IOM). Participation includes face-to-face meetings and conference calls to discuss issues of quality measurement (cost of care, episodes, care coordination, and efficiency), data aggregation, and health care price transparency.



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

Health Information Technology (HIT)-Meaningful Use/EHR

The HITECH Act, enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009, supports the adoption of electronic health records (EHR) by providing financial incentives under Medicare and Medicaid to hospitals and eligible professionals that implement and demonstrate “meaningful use” of certified EHR technology.

Under the EHR Incentive Program, eligible healthcare providers may receive incentive payments, and avoid future penalties, upon demonstrating “meaningful use” (MU) of certified EHR. The MU criteria have been developed through the Health Information Technology Policy Council (HITPC) and proposed for use in the EHR Incentive Program by the Centers for Medicare and Medicaid Services (CMS). The stages of meaningful use take providers from a process-oriented measure set in Stage 1, which requires providers to collect and report various measures, to using that collected information to make decisions about the delivery of healthcare in Stage 3. To participate as a “meaningful user,” all providers must register on the EHR incentive website, be enrolled in Medicare FFS, MA, or Medicaid, have a National Provider Identifier, and use certified EHR technology.

On August 23, 2012, CMS posted the much-anticipated final rule for Stage 2 of meaningful use of EHRs. While CMS and The Office of the National Coordinator (ONC) acknowledged the critical role of specialty providers in the meaningful use of health IT for quality improvement, there were few beneficial changes in the Stage 2 final rule.

Stage 2 retains the scope of practice exclusion for vital signs, stating that any EP who believes that all three vital signs of height, weight, and blood pressure have no relevance to his/her scope of practice is excluded from recording them. It also finalizes the provision that even if an EP records these vital signs only in exceptional circumstances, the provider is permitted to claim the exclusions for this measure. The number of mandatory objectives increases from 15 to 17, with physicians able to choose 3 of 6 elective objectives. CMS also introduced a special 3-month EHR reporting period, rather than a full year of reporting, for all providers attesting to either Stage 1 or Stage 2 in 2014.

Stage 3 meaningful use, expected to be implemented in 2016, will include demonstrating that the quality of healthcare has been improved. Stage 3 criteria have not yet been defined in detail.

Physicians who fail to demonstrate meaningful use of EHRs will suffer a 1% reduction in Medicare reimbursement in 2015. The penalty increases to 2% in 2016 and 3% in 2017 and beyond. CMS finalized the provision that EPs can avoid the penalty in 2015 if they demonstrate meaningful use in 2013. In addition, the penalty in 2015 would not apply to providers who achieve meaningful use for the first time in 2014, provided that they report this to CMS by October 1, 2014.

ASCRS submitted comments to CMS expressing our concerns about Stage 1 and Stage 2 implementation of meaningful use/EHR and will submit comments on Stage 3 as well. We support the incentives associated with the EHR MU program and remain opposed to the penalties and continue to push against the stringent timelines.

For more information on EHR/meaningful use and Stage 1 and Stage 2 provisions, please visit the ASCRS EHR/Meaningful Use webpage.



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

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 still will have the choice of two “tracks” with regard to risk, but Track 1 will not have downside risk; that is, 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

Although the final ACO rule had been widely interpreted as allowing non-primary care physicians to practice in multiple ACOs, as has become more clear over time, CMS is applying exclusivity more broadly than it had indicated in the final rule and is effectively precluding any practice that performs and bills evaluation and management services from full-fledged participation in more than one ACO – regardless of specialty. This issue was originally identified by ASCRS, and as a result, we are working closely in conjunction with a coalition of medical specialty groups and the AMA to resolve this problem with CMS.

Physicians do not have to be “participating” in an ACO in order to treat beneficiaries assigned to the ACO. Physicians and practices may also participate as “other entities,” rather than full-fledged “participants” and therefore, enter into individual contracts with more than one ACO. Contracting with the ACO as an “other entity” protects the physician’s right to be part of multiple ACOs. However, none of the patients treated by “other entities” will be counted in calculating the ACO’s savings, making it unlikely that “other entities” could receive a portion of the ACO’s shared Medicare savings. Therefore, it is important to carefully review the “other entity” agreement made with the ACO to make sure it is clear if and how the ACO plans to share savings.

It is also important to note that while Medicare beneficiaries are free to seek treatment outside the ACO, and physicians outside the ACO are free to treat them, ACOs have incentives to keep beneficiaries within their networks and some have actively discouraged beneficiaries from continuing relationships with physicians who are not a participant in the ACO.

As the process moves forward, ASCRS will continue to evaluate how this reform will impact membership. We will be focusing on issues including exclusivity, attribution, cost-benefit analyses, and continue to work with CMS in developing guidance documents aimed at both the physician/practice and ACO/hospitals clarifying ACO participation/attribution assignment and physician exclusivity, and potential pros and cons of using an “other entity” arrangement. For more information on ACO provisions and the final regulation, please visit “ACOs” in the Government Relations section of the ASCRS website.



GRASSROOTS

EYE CONTACT ADVOCACY PROGRAM

FDA Reform

510(k) Medical Device Clearance Process

The 510(k) clearance process is a medical device approval pathway designed for use with lower risk products, as well as changes made to existing products or those that are substantially equivalent to previously approved products.

Concerns about the 510(k) process, its evaluation of new devices, and increased prevalence of recalls led the FDA to take a two-pronged approach in September 2009. The FDA conducted its own internal review to analyze what changes could be made to improve consistency in the program and commissioned an independent study by the Institute of Medicine (IOM).

In August 2010, the FDA and the Center for Devices and Radiological Health (CDRH) released a two-volume report, which outlined proposed changes to the current 510(k) process. The goal of the FDA working group was to recommend reforms to the 510(k) process and make more effective use of science in regulatory decision making. The second prong of the 510(k) process evaluation, the IOM report, was released in July 2011. Ultimately, the IOM report recommended the FDA abandon 510(k) and put in place an integrated pre-market and post-market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle.

Congressman Erik Paulsen (R-MN), co-chair of the House Medical Technology Caucus, disagreed with the IOM's recommendation to scrap 510(k) altogether: "The medical technology industry is already facing unprecedented challenges—a job-stifling innovation tax and an increasingly out-of-touch FDA—and eliminating the 510(k) process would give Europe another leg up in competing for these made-in-America technologies; what the medical devices manufacturers need is consistency in the approval process, not more uncertainty." Paulsen sponsored legislation designed to improve the review process and ease bureaucratic burdens borne by device manufacturers, and many of these reforms were incorporated into the FDA Safety and Innovation Act.

FDA Safety and Innovation Act

On July 9, 2012 the President signed the FDA Safety and Innovation Act into law. The bipartisan legislation included the reauthorization of drug and device user fees, as well as reforms to the

medical device and drug approval processes proposed by Rep. Paulsen and others. The user fee programs became effective Oct. 1 -- the beginning of the fiscal year. The medical device user fees allow for a total of \$595 million in fees (plus adjustments for inflation) to be collected from industry over the five-year period of FY2013 through FY2017 and expand the definition of the types of manufacturers that must pay a registration fee. In return for payment of the assessed fees, the FDA will have new performance goals and obligations for device review activities, as well as a more structured pre-submission process and earlier interactions between the FDA and applicants and reduction in average total review time. There are still concerns about the approval process. The law also creates new user fee programs for generic drugs and biosimilars and enacts several agency reforms, including provisions aimed at improving various FDA regulatory processes and priorities, ensuring drug supply chain safety, and preventing drug shortages.

ASCERS joined with the Alliance of Specialty Medicine and a larger coalition of medical specialties in advocating for many of the reforms.

Medical Device Tax

The \$20B medical device tax was included in the Affordable Care Act (ACA) that was signed into law in 2010. The amount is based on 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

ASCERS 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.

ASCERS, 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. Bipartisan legislation recently passed in the Senate to repeal the tax and has been introduced in the House.

Off-Label

In March 2012, ASCERS, as part of the Alliance, submitted a comment letter to the FDA in response to draft guidance: *Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*, regarding the dissemination of certain off-label information in response to unsolicited requests for scientific information from health care professionals.

ASCERS raised concerns with the proposed policy for handling public unsolicited requests that

overly restricts the ability of any physician to openly discuss and respond to questions about off-label uses of drugs and devices in an educational public forum with their colleagues, as is the current custom. The letter requested that the draft guidance be amended to remove the new restrictions and continue to allow physicians to respond to their colleagues at industry-sponsored events. The FDA is unable to provide a timeframe for when the final guidance will be issued.

Physician Payments Sunshine Act

On February 1, the Centers for Medicare and Medicaid Services (CMS) released a rule that would require all pharmaceutical, medical device and biopharmaceutical companies to report transfers of value to the US government in the hopes of increasing transparency. Included in the ACA, the act will require industry to report payments, gifts or other transfers of value to physicians and physicians to disclose ownership and investment interests.

ASCRS Position

ASCRS is actively involved in FDA reform and the approval process for devices and drugs and has been engaged in conversations with FDA officials and Congress regarding 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.**