ASCRS eyeContact **Issue Brief**

Medicare Patient-Shared Responsibility

Background:

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.

ASCRS strongly supports H.R. 1650, the Medicare Patient Empowerment Act, introduced by Rep. Tom Price, MD (R-GA). This legislation currently has 6 co-sponsors. ASCRS has supported similar legislation in previous Congresses.

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 would not be forced to opt out of Medicare for two years. In addition, it would 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:

ASCRS and the medical community will work to build support for H.R. 1650 and to ensure that companion legislation is introduced in the Senate.

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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 lower provider reimbursement rates.

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

114th Congress IPAB repeal legislation:

- H.R. 1190, Protecting Seniors' Access to Medicare Act, introduced by Representatives Philip Roe, MD (R-TN) and Linda Sanchez, (D-CA). This legislation has 206 original co-sponsors.
- S. 141, Protecting Senior's Access to Medicare Act, introduced by Senator John Cornyn (R-TX). This legislation has 37 co-sponsors.

Status:

IPAB repeal has strong bipartisan support in Congress and is supported by the entire 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. ASCRS worked with the medical community to ensure this legislation was reintroduced in 2015 and continues to build support for it.

While IPAB is scheduled to go into effect in 2015, no members have been named to the board and Medicare growth has not reached the threshold that would trigger action from the board. In fact, Medicare spending growth has decreased in recent years.

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Accelerating Access to New Drugs and Devices

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.

In early 2015, Chairman Upton released a discussion draft that outlined several policy initiatives including: developing a process for qualifying and using surrogate endpoints in clinical trials to shorten the approval process; modernizing off-label communication regulations; developing a Medical Product Innovation Advisory Commission similar to the Medicare Payment Advisory Commission (MedPAC); improving clinical trial data sharing through registries; and the Advancing Innovation in Medicine (AIM) Act. In addition, Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) have begun a complementary initiative in the Senate. ASCRS joined with the Alliance of Specialty Medicine to comment and provide input on the Energy and Commerce Committee's discussion draft and provided feedback to the HELP committee on their initial exploratory questions on the issue.

Medical Device Tax

Enacted as part of the Affordable Care Act (ACA) in 2010, the medical device tax is a 2.3% excise tax 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. There is a better chance that the tax will be repealed in the 114th Congress, since Republicans now control both the House and Senate and have indicated their intention to enact changes to the ACA.

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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/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 Tack 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 supported this proposed rule in our comments to CMS and will continue to keep members updated when a final rule is released.

New ACO Model Initiative

In March 2015, the US Department of Health and Human Services annouced the Next Generation ACO Model of payment and care delivery. This new model will take on greater performance risk and also potentitally share in a greater portion of savings.

CMS reports that the Next Generation Model ACO offers ACOs a stable and predictable benchmark they must meet to share savings and has tools that will allow ACOs to have more of a relationship with their beneficiaries. For example, ACOs will be able to reward beneficiaries for receiving their care from physicians and professionals participating in the ACOs. CMS is accepting ACOs into this Next Generation ACO Model through two rounds of applications in 2015 and 2016. As more information becomes avialalbe on this ACO model, we will keep you updated.

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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 had concerns with how FDA would interpret this new law. Most importantly for ophthalmology, the bill did not include repackaging or office use in the compounding definition and left it to the FDA to determine how repackaged drugs, such as Avastin, are regulated.

FDA has now released final guidance for 503A traditional pharmacies and 503B outsourcing facilities, which states that FDA will allow both traditional pharmacies and outsourcing facilities to repackage biologics, including Avastin for ophthalmic use.

However, ASCRS and other ophthalmology stakeholder groups have concerns with the Beyond Use Dates (BUD) that the draft guidance lays out. The draft guidance provided for a BUD of four hours or equal to the time within which the opened product is to be used as specified on the approved labeling, whichever is shorter, for traditional compounders. The BUD can be extended to 24 hours if microbial challenge studies are performed. The same BUDs apply to outsourcing facilities, but can be extended to five days if the outsourcing facility conducts adequate compatibility studies on the container closure system (the syringe) to ensure product integrity.

In ASCRS' discussions with providers and compounding stakeholders, the conclusion has been that the BUD timeframe is extremely short. Specifically, there are concerns that the 5-day expiration date will severely limit the use of Avastin. ASCRS is now working in a coalition with

other ophthalmology groups to notify the FDA of the issues surrounding these short BUD timeframes and asking these to be extended in the final guidance document. We will continue to keep you updated on this issue.