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ASCRS Government Relations
www.ascrs.org/legislative-and-regulatory
703-591-2220
Increasing the Value of Post-Operative E/M Visits in 10- and 90-day Global Surgery Codes

In the 2020 Medicare Physician Fee Schedule (MPFS) proposed rule, the Centers for Medicare and Medicaid Services (CMS) proposes significant modifications in coding and increased reimbursement for standalone E/M services in 2021 but is not proposing to make corresponding increases to the value of post-operative E/M services in 10- and 90-day global surgery codes. ASCRS strongly opposes CMS’ proposal to increase the standalone E/M services while maintaining the current value of post-operative E/M visits in 10- and 90-day surgical global packages.

In response, ASCRS has joined with the American Medical Association (AMA) and the surgical community to advocate to CMS that the current proposal disrupts the relativity of the physician fee schedule and runs afoul of the statute requiring that Medicare reimburse physicians for the same services furnished, regardless of the specialty. In addition, there is nothing in MACRA that precludes CMS from updating the values. ASCRS and the surgical community are urging the agency to increase the value of the post-operative E/M visits in the global period when it finalizes the fee schedule rule in November 2019.

Background

In the 2020 MPFS proposed rule, CMS is proposing to accept the AMA Relative Value Scale Update Committee (RUC) recommendation to increase the value of standalone E/M office visits beginning in 2021 but did not accept the RUC recommendation to also increase the value of post-operative E/M visits that are bundled into 10- and 90-day global surgery codes. Currently, Medicare pays surgeons and other specialists a single fee (global payment) when they perform major or minor surgery (10- or 90-day), such as cataract surgery. This single fee covers the costs of the surgery plus related care one day prior to surgery and follow-up care within a 10- or 90-day timeframe. If CMS were to increase the value of the post-op E/M visits in the global codes, this will offset much of the proposed reduction to the re-valuation of cataract surgery. In accordance with the Medicare statute, when E/M codes have been revalued in the past—three times since the inception of the fee schedule in 1992—CMS has also increased the value of the post-operative visits in the global codes.

ASCRS and the surgical community strongly oppose CMS’ proposal for the following reasons:

- **Disrupts the relativity in the fee schedule:** Changing the values for some E/M services, but not for others, disrupts the relativity mandated by Congress as part of the Omnibus Budget Reconciliation Act (OBRA) of 1989 (P.L. 101-239), which implemented the Resource Based Relative Value Scale (RBRVS) in 1992 and refined over the past 27 years. Each time the payments for new and established office visits were increased, CMS also adjusted the bundled payments to account for the increased values for the E/M portion of the global codes.

- **Creates specialty differentials:** Per the Medicare statute, CMS is prohibited from paying physicians differently for the same work. Care provided during post-operative visits represents the same work, practice expense, and malpractice costs as furnishing a standalone E/M visit.
Failing to adjust the global codes and paying some doctors less for providing the same E/M services is a violation of the law.

- **Violates MACRA Statute Related to Data Collection on Global Surgery Services:** CMS is in the process of gathering information on global surgery codes as mandated by the MACRA statute and therefore asserts that it will not modify the values of visits in the global surgery payment until it can verify that the number and level of visits are accurate. However, while the MACRA statute gave CMS the authority to study global surgery codes, it also expressly indicates that CMS should continue to update individual code values. Since the standalone E/M codes were re-valued, the post-operative E/M visits included in the global codes should be as well. If CMS believes that specific codes are overvalued, then it should refer those codes as potentially misvalued to RUC for review, rather than applying this policy broadly to all surgical services.

- **Ignores RUC recommendations:** The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10 or 90 days.

**ASCRS, AMA, and Surgical Community Advocacy**

ASCRS recently joined with the American Medical Association (AMA) and the surgical community to meet with CMS and recommend that the agency increase the value of the post-operative E/M visits in the global period when it finalizes the fee schedule rule in November. We noted that surgeons providing post-operative visits in the global period are performing the same level of work as if the visit were a standalone E/M visit and therefore, should be reimbursed at the same level as mandated by the Medicare statute. Furthermore, failing to increase the values of E/M visits in the global periods disrupts the relativity of the physician fee schedule and violates the Medicare statute that mandates physicians be paid the same for performing the same services, regardless of specialty. In addition to meeting with CMS, ASCRS has joined with the AMA and 52 medical specialty organizations in a letter to CMS reiterating our call to increase the post-operative values.

In the House of Representatives, Congressmen Ami Bera, MD (D-CA) and Larry Bucshon, MD (R-IN), both physicians, took the lead on a bi-partisan House letter, along with 23 additional members of the House of Representatives to CMS urging the agency to apply the increased value of standalone E/M codes to the E/M visits included in the 10 and 90 day Global Codes.

**Increasing Values for Intermediate and Comprehensive Eye Exam Codes**

ASCRS is also advocating that the values for intermediate and comprehensive eye exam codes should increase to reflect the updated values of E/M office visit codes for 2021. CMS recognized that eye exam services are linked to E/M services in the 2020 MPFS proposed rule and solicited comment on whether they should also be increased. ASCRS has submitted comprehensive comments to CMS on the proposed rule, and explained that because of similar work, practice expense and malpractice costs of furnishing the exams, the eye codes are largely based on the value of the office visit E/M codes and therefore, should be increased along with the office visit codes to preserve the relativity of these services.

**Next Steps**

We will alert members when the final rule is released in November.
Extend Positive Payment Updates to the Conversion Factor and A-APM Bonus
Maintain a Viable Medicare Part B Fee-for-Service Option and MIPS

ASCRS urges Congress to extend positive physician payment updates to the conversion factor and Advanced Alternative Payment Models (A-APM) bonus payments—which are scheduled to expire this year—to ensure that Medicare fee-for-service (FFS) and the programs under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) continue to be viable options. ASCRS thanks Congress for enacting MACRA technical corrections into law last year. While these provisions significantly improved the ability of Medicare physicians, particularly specialists, to continue to participate in quality improvement activities, and specifically in the Merit-Based Incentive Payment System (MIPS), additional technical corrections are needed to streamline and simplify the MIPS program and give CMS the flexibility to modify participation thresholds.

SUMMARY OF LEGISLATIVE REQUESTS
To ensure that fee-for-service and the programs under MACRA continue to be viable options, ASCRS urges Congress to enact the following legislative changes to the statute:

• **EXTEND POSITIVE PAYMENT UPDATES TO THE CONVERSION FACTOR**

  MACRA included five years of much-needed 0.5% positive payment updates for all physicians. Beginning in CY 2020, however, there is a freeze for six years until 2026, where physicians remaining in MIPS receive a 0.25% update, while those in A-APMs receive a 0.75% update. Despite the future updates, physicians will struggle to provide care at the current payment level since, according to a recent Medicare Trustee’s report, inflation is expected to increase physician costs by about 2.2% while, at the same time, physicians are continuing to ramp up participation in the Quality Payment Program (QPP). Congress must extend positive payment updates to the conversion factor to ensure practices can continue to make investments in the tools needed to participate in the QPP.

• **EXTEND A-APM BONUS PAYMENTS**

  In addition, Congress should extend the 5% bonus for physicians participating in A-APMs. While there are currently only limited opportunities—and no ophthalmology-specific models—for specialists to participate in A-APMs, CMS and other stakeholders are expected to increase the pace of developing and testing new models over the coming years. Current Advanced APM models are primary care-focused and not well suited for specialists, such as ophthalmologists, but if CMMI approves new models developed by specialists, more specialists will want to implement them. Initially, however, if specialists can participate in new models, the financial risk and additional administrative costs of implementing the models will need to be off-set by the participation bonus. If Congress allows the bonus to expire after 2022, it will make it difficult for physicians to take on the additional risk and administrative costs associated with moving toward new and
innovative models. **We encourage Congress to extend the bonus for an additional six years.**

- **ENACT ADDITIONAL MACRA TECHNICAL IMPROVEMENTS**

  ASCRS continues to recommend that Congress make additional technical corrections to the MACRA statute to streamline and simplify the scoring in the MIPS program. Currently, each of the four categories of MIPS functions as its own program with unique scoring methodologies that can be difficult for physicians to understand. We recommend Congress give CMS the authority to make scoring more flexible, such as allowing multi-category credit for certain activities. In addition, CMS should have the authority to center physician participation around specific episodes of care or conditions relevant to the physician’s—in particular, a specialist’s—practice.

  In addition, we recommend the following technical fixes to the program:

  - Allow CMS to set the MIPS performance threshold at an appropriate level, rather than the mean or median of the previous year’s score, and give CMS the authority to set multiple performance thresholds, such as a separate one for small and rural practices;
  - Give CMS authority to modify the participation thresholds for participating in A-APMs and exclude Part B drug costs from APM financial risk calculations;
  - Modify the Promoting Interoperability category to award credit for using technology, such as qualified clinical data registries like the IRIS Registry, that interact with certified EHRs;
  - Modify the Cost category by removing the primary care-based total per capita costs measure that potentially holds physicians responsible for the cost of care they did not provide and remove the requirement that episode-based measures account for at least 50% of Part A and B expenditures to ensure they are valid and reliable;
  - Allow pay-for-reporting on new measures or when significant refinements to a measure or composite have been made; and
  - Provide authority for the Physician-focused Payment Model Technical Advisory Committee (PTAC) to provide technical assistance and data analyses to stakeholders who are developing proposals for its review.

**BACKGROUND**

Ophthalmologists treat only one organ, the eye, and generally only coordinate care with other eyecare professionals. This specialization has led to efficient care delivery, eliminating variations in cost and quality for key conditions, such as cataracts. To demonstrate their commitment to continued quality improvement and resource efficiency, most ophthalmologists participate in the MIPS program, allowing them to focus on measures that are relevant to their practice and specialty, and those that are within their control. In addition, most ophthalmologists participate in the IRIS Registry, which allows them to track performance and report on clinically relevant measures. Current APM models are primary care-focused and do not include any ophthalmology measures.
They do not allow the few ophthalmologists who do participate to report any measures relevant to their practice.

**Without available A-APMs, ophthalmologists will continue to participate in MIPS. Therefore, a continuation of positive payment adjustments to the conversion factor is necessary to assist practices in meeting the costs of investing in and continuing to participate in the program.**

ASCRS is concerned that recent proposals included in the President’s FY 2020 budget proposal, and recent comments by Administration officials that fee-for-service is “antiquated,” are aimed at eliminating fee-for-service and transitioning physicians into primary care-focused A-APMs or evaluating them in large virtual groups on population-based measures that do not reflect specialty care. The Administration’s efforts to transition physicians into A-APMs is especially frustrating for specialists, since CMMI has not elected to implement innovative models developed by specialties and approved by the PTAC.

**We urge Congress to preserve a viable fee-for-service option, while also encouraging CMMI to implement specialty developed alternative payment models. In addition to further MACRA technical corrections, the physician payment freeze should be replaced with positive payment updates to the conversion factor, and the A-APM bonus should be extended.**
MACRA Regulatory and Legislative Reforms

ASCRS supports the goals of the Medicare Access and CHIP Reauthorization Act (MACRA) and continues to urge Congress to make limited needed changes to the statute, while also monitoring CMS’ implementation to ensure its intent is fully realized and preserved. ASCRS is advocating that Congress make legislative changes to implement positive payment adjustments for physicians to replace the payment freeze over the next six years, beginning in 2020, and to extend the 5% bonus for physicians participating in advanced alternative payment models (A-APMs). Additionally, ASCRS strongly opposes many proposals in the 2020 Medicare Physician Fee Schedule (MPFS) proposed rule pertaining to the Quality Payment Program (QPP), including implementing a new mandatory participation pathway: Merit-Based Incentive Payment System (MIPS) Value Pathways (MVPs), inclusion of FDA-approved pass-through drugs in the cataract surgery episode-based cost measure, and removing “topped-out” ophthalmology measures.

Background

Medicare Physician Payment

As part of the AMA MIPS Workgroup Medicare Task Force, and advocacy with the Alliance of Specialty Medicine, ASCRS is asking Congress and CMS to make the following legislative technical changes to the MACRA statute:

- **Extend Positive Payment Updates:** Extend the 0.5% positive payment update originally authorized under MACRA for six additional years. Under current statute, the update falls to 0.0% for six years beginning in 2020 through 2026.

- **Extend A-APM Bonus Payments:** Extend the 5% bonus for physicians participating in A-APMs. If Congress allows the bonus to expire after 2022, it will eliminate the incentive for specialty physicians to move toward new and innovative models. We encourage Congress to extend the bonus for an additional six years.

2020 MPFS Proposed Rule – Quality Payment Program

In July 2019, CMS released the 2020 MPFS proposed rule, which includes the proposed 2020 QPP. Specific issues ASCRS is concerned with include the following:

- **Mandatory MVPs:** CMS is proposing a new mandatory participation pathway beginning in 2021 called MVPs that would require physicians to report on a specific set of measures and activities related to a particular condition or procedure identified by CMS. ASCRS strongly opposes CMS’ MVPs proposal because it would be a mandatory requirement and would eliminate a physician’s ability to determine which measures are appropriate for his/her practice and patient population. In addition, the MVPs include problematic population-health measures, burdensome patient-reported outcome measures, and continues the separate scoring methodology for the four MIPS categories.

- **FDA-approved pass-through drugs in the cataract surgery episode-based cost measure:** Currently, CMS includes one FDA-approved pass-through drug in the cataract surgery episode-based cost measure. ASCRS maintains that including any drug on pass-through defeats the purpose of pass-through to provide un-biased utilization data on the drug. When new, innovative higher-cost drugs come onto the market, CMS pays for them
separately—once pass-through status is determined—for up to three years. This gives time for the drug to be introduced to the market, and when the pass-through status has expired, CMS uses the utilization data to include in the formula for the updated facility payment to account for the cost of the drug in the bundled facility payment. As a result of including the cost of pass-through drugs in the cataract cost measure, many surgeons have discontinued use of pass-through drugs so as not to negatively impact their Cost score.

- **Topped-out measures:** CMS is proposing to remove two cataract surgery outcome measures (192 and 388) that track surgical complications that CMS deems “topped out”—meaning that overall performance is consistently high—and should no longer be reported. Removing these measures would limit ophthalmologists’ ability to track their outcome rates relative to their peers. ASCRS urges CMS to retain the current quality measures and continue to award credit for maintaining high quality. Continuing to measure even the most successful procedures, such as cataract surgery, ensures that surgeons are continuing to achieve positive outcomes.

- **Specialty-specific A-APMs:** We continue to advocate for the development of specialty-specific Advanced APMs, as current models are primary care-based and are not appropriate for specialists, such as ophthalmologists, nor encourage their participation.

- **“All-or-nothing” scoring:** ASCRS continues to oppose the all-or-nothing scoring methodology in the Promoting Interoperability category of MIPS. Participants should have the opportunity to earn points for focusing on the measures that are most relevant to their practice, rather than having to report on all measures.

ASCRS submitted comments to CMS on the 2020 MPFS proposed rule and is working with the surgical community to ensure successful participation in the QPP.

**Next Steps**
ASCRS will work with the medical community to advocate for additional changes in the statute and future rulemaking. We will alert members when the final rule is released in November.
Regulatory Relief

ASCRS ASOA seeks to advocate for regulatory changes that will alleviate the administrative burden on practices, so that physicians can focus on providing high-quality care to patients.

Background
For several years, regulatory agencies, such as the Centers for Medicare and Medicaid Services (CMS), have implemented programs that increase the time spent, documentation necessary, and administrative costs to practices. In response to the Trump Administration's initiative to reduce regulatory burden across all sectors of the economy, ASCRS ASOA and the medical community have identified several key areas where CMS could take steps to reduce the burden on physicians and practices. In October 2017, CMS announced a new “Patients Over Paperwork” initiative to implement these recommended reforms, beginning with the 2018 final rules for the Quality Payment Program (QPP), Physician Fee Schedule, and ASC Payment.

Relief from Burdensome Provisions of MACRA
ASCRS, the Alliance of Specialty Medicine, the American Medical Association (AMA), and the medical community have already achieved considerable relief for physicians in the 2017, 2018, and 2019 QPP final rules. In addition, we successfully advocated that Congress make certain technical fixes to the MACRA statute.

To relieve burden on physicians, CMS extended the MIPS transition period through 2019, so that physicians and groups can avoid the 2021 7% penalty as they fully transition to the MIPS program. In addition, CMS finalized several policies to assist small practices, such as a small practice bonus on the MIPS final score, Quality and Improvement Activities category scoring accommodations, and a hardship exemption for the Promoting Interoperability category.

In addition, ASCRS ASOA successfully advocated for a few key technical corrections to the MACRA statute to provide regulatory relief. These changes include: giving CMS the authority to extend transitional flexibility for three additional years so CMS does not have to use the mean or median of the previous year’s scores to set the performance threshold; providing authority to reduce the weight of the Cost category below 30% for three additional years; delaying the implementation of scoring improvement in the Cost category until 2022; and excluding Part B drugs from MIPS penalties or bonuses. For 2019, CMS implemented these provisions by extending the transition period and keeping the Cost category weight low at 15% of the final score.

Please see the ASCRS Issue Brief “MACRA Legislative and Regulatory Reforms” for full details on our recommendations to CMS and Congress.

Other Key Areas for Regulatory Relief
In addition to seeking relief from the penalties listed above, ASCRS ASOA and the medical community are identifying more areas for potential changes. Current efforts include, but are not limited to:
  - EHR interoperability
  - Prior authorization and step therapy
  - Medicare Advantage narrow networks and audit requests
  - Drug prices and compounding
We partnered with the Alliance of Specialty Medicine to develop a survey on access to care, specifically seeking information from members about how the increased use of prior authorization and rising drug costs may be limiting beneficiaries’ access to care. Results from the survey are being used to support our advocacy efforts. ASCRS ASOA has also provided CMS with examples of onerous MA plan chart audit requests to demonstrate the burden these requests place on small practices.

*Please see the separate issue brief on “Step Therapy in Medicare Advantage and Part D” for full details on ASCRS’ advocacy on this issue.*

**Next Steps**
ASCRS will continue to work with the medical community to advocate for our recommended changes to provide relief.
Step Therapy in Medicare Advantage and Part D

In an effort to reduce high prescription drug costs, the Trump administration announced in 2018 a new policy that was effective January 1, 2019, to permit Medicare Advantage (MA) Plans to begin using step therapy for Part B drugs administered in the office or facility. Following the policy announcement, CMS released a final rule, opposed by ASCRS and the medical community, which codifies the use of step therapy in MA plans and expands step therapy and prior authorization in Part D plans effective on January 1, 2020.

Background
Step therapy, also known as “fail first,” is a cost-containment strategy that requires physicians to prescribe an insurer’s preferred treatment first, and only covers more expensive treatments if the patient does not respond to the initial treatment. Previously, MA plans were prohibited from using step therapy; however, as part of the overall effort to reduce the costs of prescription drugs, CMS announced in August 2018 that plans may begin using step therapy for the 2019 benefit year.

The new guidance strongly encourages insurers to notify beneficiaries if they will incorporate step therapy in MA or Part D plans, and step therapy can only be used for new prescriptions. To encourage beneficiaries to participate in these programs, the guidance allows plans to offer rewards, such as gift cards, in exchange for participation. Rewards may not be made in the form of monetary or cash rebates, and the value must be reasonable or appropriate. CMS will consider a reward or incentive as reasonable or appropriate value if it is equivalent to more than half the amount saved on average per participant as a result of participating in step therapy.

The new guidance is targeted at Part B drugs administered in the office or facility, but also permits MA plans that offer Part D drug coverage to use step therapy to require a Part D drug prior to using a Part B drug, or vice versa. Plans’ use of step therapy must continue to comply with national and local coverage determinations.

In additional guidance, CMS stated that plans using step therapy would be able to require the use of off-label drugs, such as Avastin, if they were less expensive than the on-label drug. In addition, CMS is strongly encouraging plans that step therapy can only be used for new prescriptions, and patients who are well controlled with an existing treatment cannot be made to change to a less expensive treatment, even if they change plans.

In May of 2019, CMS released a final rule that implements ASCRS- and ophthalmic community-opposed policies to allow MA Plans to implement step therapy for Part B drugs administered in the physician office, as well as expands step therapy and prior authorization for Part D plans.

Prior to the release of the final rule, ASCRS, along with the American Academy of Ophthalmology, met with Health and Human Services (HHS) Secretary Alex Azar in January 2019 to reiterate our opposition to the use of step therapy. We explained that these policies will prevent or delay beneficiary access to the most appropriate treatment, which could have the unintended consequence of worsening a patient’s condition. Following the meeting, we submitted a list of suggested reforms and patient protections that should be implemented if plans use step therapy. In addition, ASCRS joined the Alliance of Specialty...
Medicine, the medical community, and a broad coalition of medical and patient advocacy groups in meetings and letters to CMS, and to Congress, opposing the use of step therapy.

Following our advocacy, CMS did make one modification to the step therapy policy in the final rule. Specifically, CMS extended the lookback period—during which an insurer must determine whether the patient has tried and failed a less-expensive treatment before applying step therapy to a more expensive, new drug—from the proposed 108 days to a full year. This change is a result of advocacy by ASCRS and AAO during the meeting with HHS Secretary Alex Azar.

Additionally, CMS finalized its proposal to require Part D plans to develop real-time benefit tools (RTBTs) to integrate with prescribers’ EHR systems as a tool to help inform patients about their formulary options and potential out-of-pocket costs. CMS is requiring that each Part D plan adopt one or more RTBTs that are capable of integrating with an e-prescribing system or electronic health record (EHR) no later than January 1, 2021.

Legislation

Bipartisan legislation to address step therapy has been introduced in both the House and Senate. In April 2019, Representatives Raul Ruiz, MD (D-CA) and Brad Wenstrup, DPM (R-OH) introduced the Safe Step Act, a bipartisan bill to improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them. Following its release, Senators Lisa Murkowski (R-AK), Doug Jones (D-AL), and Bill Cassidy, MD (R-LA) introduced a companion bill in the Senate that would limit the use of step therapy by requiring group health plans to provide an exception process for any medication step therapy protocol. Additionally, insurers would be required to implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.

Next Steps

ASCRS will continue to oppose the use of step therapy and will work with the medical community to advocate to ensure Medicare beneficiaries have access to care.
Medicare Patient Shared Responsibility

ASCRS supports a patient’s right to obtain medical services from the physician of his or her choice by adopting additional Medicare payment options. Currently, physicians must opt out of Medicare for two years if they enter into a private contract with a Medicare patient. Therefore, ASCRS supports passage of the Medicare Patient Empowerment Act.

In October 2017, CMS issued a Request for Information (RFI) on a “new direction” for its Center for Medicare and Medicaid Innovation (CMMI) and asked for comments on a possible demonstration to allow Medicare patients and physicians to contract privately. ASCRS supports a demonstration based on the policies included in the Medicare Patient Empowerment Act.

Background

In the 114th Congress, H.R. 1650/S. 1849, the Medicare Patient Empowerment Act, were introduced by Rep. Tom Price, MD (R-GA) in the House and Sen. Lisa Murkowski (R-AK) in the Senate. ASCRS supported this legislation and has supported similar legislation in previous Congresses. The Medicare Patient Empowerment Act would allow physicians and patients to contract freely on a case-by-case basis, without penalty, for Medicare services. Medicare beneficiaries would 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.

Bill Status

ASCRS and the medical community worked to build support for H.R. 1650 and S. 1849, but time ran out in the 114th Congress. Under the Medicare Access and CHIP Reauthorization Act (MACRA), physicians now have the ability to automatically renew their opt-out status every two years.

In June 2016, House Republicans released their Better Way plan, which was designed to repeal and replace the Affordable Care Act (ACA). The plan included a demonstration on the Medicare Patient Empowerment Act that ASCRS supports, but there was no mention of it in the American Health Care Act, introduced in March 2017 by House Republicans to repeal and replace the ACA.

In October 2017, Rep. Pete Sessions (R-TX) re-introduced the Medicare Patient Empowerment Act, H.R. 4133, in the House of Representatives. At the beginning of November, ASCRS sent a letter to Rep. Sessions in support of H.R. 4133. We also sent a support letter in conjunction with the Alliance of Specialty Medicine.

In November 2018, at the request of ASCRS, ophthalmologist Sen. Rand Paul, MD (R-KY), re-introduced S. 3610, the Senate version of the Medicare Patient Empowerment Act. However, with the lame duck session nearing an end, it is unlikely that there will be any movement on the bill. Sen. Paul has indicated that he will re-introduce it in the 116th Congress, as well.

Possible CMS Innovation Center Private Contracting
CMS’ RFI on a new direction for CMMI, which is tasked with developing policies and models to improve quality and reduce costs, seeks comments on ways to encourage consumer directed care and market-based innovation models, including allowing Medicare beneficiaries to contract directly with physicians. In response to the RFI, ASCRS•ASOA reiterated its ongoing support for a viable private contracting option envisioned by the Medicare Patient Empowerment Act. We urged the Innovation Center to develop a demonstration project based on the policies included in the bill.
Off-Label Communication

ASCRS supports efforts to ensure that ophthalmologists have access to truthful and non-misleading information about off-label uses of medical products. We support the free-flow of information between physicians and drug and device manufacturers.

Background
Physicians have the authority to prescribe drugs for any reason they believe will benefit the patient, regardless of whether the use is on- or off-label. However, the Food and Drug Administration’s (FDA) current regulations regarding off-label communications impede physicians’ quests for scientific knowledge and ability to care for their patients by interfering with the flow of information from drug and device manufacturers to practitioners. The FDA does not allow pharmaceutical companies to actively distribute key clinical information, even if it is related to the on-label indication, unless it is explicitly referenced in the package insert. Therefore, any new information such as observational data, subpopulation information, comparative data derived from clinical trials other than randomized controlled trials, and pharmacoeconomic or comparative cost data cannot be proactively shared with clinicians unless such data is directly referenced in the package insert. Furthermore, current off-label regulations limit physician discussions between one another in public forums and industry sponsored events.

After increased pressure from industry stakeholders and multiple legal setbacks, the FDA announced they would undergo a thorough review of their regulations governing off-label communication. ASCRS and the Alliance of Specialty Medicine have long called for overhauling off-label communication regulations.

ASCRS Advocacy
In November 2016, past ASCRS President, Doyle Stulting, MD, PhD, testified at an FDA hearing on behalf of ASCRS and member organizations of the Alliance of Specialty Medicine and communicated the following:

- FDA must open the lines of communication between manufacturers and practitioners to help facilitate development and dissemination of accurate information about off-label use;
- FDA must stop restricting important new information about off-label use of medical products, as it impedes the knowledge of physicians, reduces treatments options for patients, and harms patient outcomes; and
- FDA should add a paragraph to all drug and device insert labels that indicates scientifically valid data may become available to justify new uses, dosages, contraindications, or other modifications of the information contained herein.

Following the testimony, the Alliance of Specialty Medicine updated their position statement to reflect our recommendation to amend language on product label inserts. ASCRS and the Alliance have submitted written comments in support of these recommendations.
Legislation
In the previous Congress, two bills were introduced that would support the free-flow of information between physicians and drug and device manufacturers. First, the Medical Product Communications Act (H.R. 1703), introduced by Rep. Morgan Griffith (R-VA), would have given drug and device manufacturers the ability to communicate truthful and non-misleading information about their products that is not referenced in the FDA-approved label on a medical product to physicians.

Additionally, the Pharmaceutical Information Exchange Act (H.R. 2026), sponsored by Rep. Brett Guthrie (R-KY), would have improved patient access to emerging medication by clarifying the scope of permitted healthcare economic and scientific information communications between biopharmaceutical manufacturers and population health decision-makers.

The House Energy and Commerce Health Subcommittee met and heard testimony on both bills in 2018. There was general support from Republicans and opposition from Democrats. Since the bills were not enacted in the previous Congress, they must be reintroduced in the current Congress. ASCRS is working to ensure similar legislation is introduced in the current Congress.

FDA Actions
The FDA has created a taskforce to examine off-label communication regulations. Speaking recently at a conference, an FDA representative announced that it has adopted a risk-based approach to enforcing off-label communication regulations. The FDA risk-based approach identifies violations that pose significant public health risks rather than technical or insignificant violations. ASCRS and other stakeholders are still awaiting a formal release of a new policy. However, we remain optimistic that these comments foreshadow a larger change in off-label communication policies. ASCRS will continue to advocate for lifting restrictions on the dissemination of off-label information.

State Off-Label Laws
On March 21, 2017, House Bill 2382, which passed the state House and Senate unanimously, was signed into law by Arizona Governor Doug Ducey (R) allowing drug and medical-device companies to “engage in the truthful promotion” of drugs and devices to medical professionals. The new Arizona law will allow drug company representatives to share information with doctors or other licensed prescribers that is "not misleading, not contrary to fact, and consistent with generally accepted scientific principles."

On May 3, 2018, Tennessee became the second state to enact a law that allows pharmaceutical manufacturers, or their representatives, to engage in truthful promotion of off-label uses. These bills are significant because they are being touted as a model for other states to follow, and an opportunity to set federal precedent in the U.S. Supreme Court.

Next Steps
ASCRS will continue to work with the Alliance of Specialty Medicine to advocate for lifting restrictions on the dissemination of off-label information.
Drug Compounding and Repackaged Biologics

ASCRS supports the Food and Drug Administration’s (FDA) efforts to ensure the safety and sterility of compounded and repackaged drugs. Most recently, ASCRS successfully advocated for revised policies that seek to improve physicians’ access to compounded drugs for office-use to treat patients that present with emergent conditions. Additionally, we have been successful in advocating for continued access to repackaged biologics, such as Avastin. However, we remain concerned with the FDA’s implementation of the compounding provisions of the Drug Quality and Security Act (DQSA) and its impact on the availability of compounded drug products. Specifically, we are concerned with the FDA’s final guidance to only include substances on the 503B Bulks List if there is no FDA-approved drug available and if there is a clinical need for the compounded drug, as this action may limit patient and physician access to compounded drugs.

Office-Use
When the DQSA was enacted in November 2013, it created a new category of pharmacies, 503B outsourcing facilities, that may compound without a patient-specific prescription and voluntarily submit to stricter FDA oversight. Pre-existing 503A traditional compounders may compound a drug upon receipt of a valid prescription for an identified individual patient, or in limited quantities before receipt of a valid prescription order for an identified individual patient.

In December 2016, the FDA finalized a Guidance for Industry (GFI) for 503A traditional compounders that expressly prohibits “office-use” compounding without a patient-specific prescription. ASCRS does not support the GFI and has sent several letters to the FDA urging it to prioritize the needs of patients by preserving physician access to compounded drugs for office-use. Additionally, ASCRS continues to work as part of the DQSA Coalition, composed of more than 30 organizations, to provide input to the FDA, to State Boards of Pharmacy, and to Congress about our concerns with the FDA’s implementation of the DSQA.

In response to ASCRS and medical community advocacy, a bipartisan group of 65 House members sent a letter to FDA commissioner Scott Gottlieb, MD, expressing significant concerns with the final guidance document, Prescription Requirement Under Section 503A. Shortly after, ASCRS and others in the medical community testified at the FDA on physician access to compounded drugs from traditional 503A compounders. We explained that while physicians may have access to compounded drugs from 503B outsourcing facilities without a patient-specific prescription, outsourcing facilities often do not produce drugs in the limited quantities or ophthalmic solutions required by ophthalmologists due to costs involved with testing. ASCRS and others in the ophthalmic community stressed the importance of having small quantities of these drugs on hand when patients present with emergent conditions and urged the agency to work toward a pathway to ensure patients do not lose access to these sight-saving drugs.

In response to ASCRS and medical community advocacy, the FDA issued a revised draft guidance for 503B outsourcing facilities that addresses our concerns and seeks to improve 503B outsourcing facilities’ ability to produce compounded drugs for office-use. In the document, the FDA has revised requirements related to sterility testing, release testing, and BUDs, that will make it easier for 503Bs to compound small
batches of drugs.

In addition, the FDA will hold a public meeting on May 21, 2019, to solicit comments from stakeholders on the potential impact the policies will have on drugs for office stock from 503B outsourcing facilities. ASCRS will attend and provide a statement during the meeting.

**Bulk Drug Substances**

In March 2018, the FDA released a draft guidance on how it will evaluate drug substances that may be used for compounding in 503B outsourcing facilities. In this draft guidance, the FDA proposed only to include drug substances on the 503B Bulk List if there was no FDA-approved drug available and there was a clinical need for the compounded drug. ASCRS was concerned that this policy could limit access to many ophthalmic compounded drugs from 503B outsourcing facilities.

In response to the draft guidance, ASCRS submitted comments to the FDA encouraging it to recognize that it is not possible to compound many ophthalmic drugs using bulk drug substances that are components of FDA-approved drugs. ASCRS urged the FDA to maintain access to bulk drug substances that are used for compounding ophthalmic drugs in 503B outsourcing facilities. Additionally, we sent joint letters with the ophthalmic community to the FDA asking it not to limit access to drugs produced in 503B outsourcing facilities with federal oversight that offer greater assurance of quality, and included a list of bulk drug substances that should be on the 503B Bulks List.

In March 2019, the FDA released a final guidance on the evaluation of bulk drug substances for compounding in 503B outsourcing facilities with no changes to the evaluation process for including bulk substances on the 503B list. ASCRS remains concerned that this may limit access to drugs used in ophthalmology, as many FDA-approved drug products do not have the same strength, routes of administration, or formulation needed to treat ocular disease—making it impossible to produce the ophthalmic product without compounding from a bulk substance. ASCRS is working with the ophthalmic community to nominate bulks substances to the 503B Bulks List to ensure physicians have access to these important drugs.

Additionally, we continue to work with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), which is collaborating with the FDA to help research and evaluate the list of permitted bulk drug substances used in compounding by 503B outsourcing facilities. ASCRS is providing information about the use of bulk drug substances and their importance in the practice of ophthalmology.

**Repackaged Biologics**

In February 2015, the FDA released draft guidance for repackaged biologics, including Avastin, for outsourcing facilities. The draft guidance provided for a Beyond Use Date (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. The BUD could be extended to five days if the outsourcing facility conducted adequate compatibility studies on the container closure system (the syringe) to ensure product integrity.

ASCRS discussed the proposed draft guidance with providers and compounding stakeholders, and the conclusion was the BUD timeframe was extremely short. Specifically, there were concerns that the five-day expiration date would severely limit the use of Avastin. ASCRS and others in the ophthalmic community testified before the FDA, recommending the BUDs be extended, and prompted a bipartisan letter from Congress urging a more individualized approach to BUDs.
In January 2018, following extensive advocacy by ASCRS and the ophthalmic community, the FDA released a final guidance on repackaged drugs that reflects our recommendations to extend the BUDs for repackaged drugs. The final draft guidance allows outsourcing facilities to extend the BUD of repackaged drugs, such as Avastin, if additional sterility testing is undertaken. While ASCRS supports the pathway to extend BUDs for repackaged biologics past 24 hours, if additional testing is done, ASCRS is concerned that smaller outsourcing facilities will find it difficult to meet these requirements due to costs involved with additional testing. We are continuing to advocate for a more individualized approach to BUDs.

Next Steps
ASCRS will continue to work with the medical community to advocate for our recommended changes to ensure physicians have access to essential drugs.
Accountable Care Organizations (ACOs)

ACOs are alternative payment models designed to lower total overall healthcare-associated expenditures while improving quality of care. They are entities 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. Originally authorized under the Patient Protection and Affordable Care Act, CMS created two voluntary initiatives in 2011 to increase participation in and adoption of ACOs: the Medicare Shared Savings Program (MSSP) and the Advance Payment Model.

In 2015, the Medicare Access and CHIP Reauthorization Act (MACRA) increased incentives for physicians participating in certain Advanced Alternative Payment Models (APMs) that incorporate two-sided risk, which include some ACOs.

In its 2017 MACRA final rule, CMS listed MSSP Track 2 and 3 and Next Generation ACO, and in 2018 added Track 1 Plus ACOs as advanced APMs eligible for additional bonus payments. CMS excluded Track 1 ACO models from incentives because they do not meet the MACRA criteria to incorporate downside risk. However, physicians participating in Track 1 ACOs will receive credit under the Merit-Based Incentive Payment System (MIPS) by reporting quality measures through the ACO and receiving full credit for improvement activities. Track 1 ACO participants will be required to report EHR measures for the Promoting Interoperability category individually. Details for participation are discussed below.

In October 2017, CMS released a request for information on a new direction for the Center for Medicare and Medicaid Innovation (CMMI). While the RFI stated CMS’ new intention to focus on voluntary models and incorporate specialty perspectives, CMS is still dedicated to moving physicians out of fee-for-service Medicare and into APMs, such as ACOs. In response, ASCRS noted that there are currently no ophthalmology-specific APMs, and when ophthalmologists do participate in APMs, it is generally in Track 1 ACOs. Furthermore, by CMS’ own estimates in the 2017 MACRA final rule, only 153, or 0.7% of ophthalmologists nationwide, will participate in Advanced APMs. We urged CMS to maintain a fee-for-service option.

Medicare Shared Savings Program

Under the MSSP, providers enter 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 up front which Medicare beneficiaries are likely to be part of their system), while lowering costs, in return for a share of the savings. 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. Under the final ACO rule, participating ACOs still will have the choice of two “tracks” for 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. A later 2014 rule allowed ACOs participating in Track 1 to continue the program after their initial three-year agreement, but at a lower sharing rate than the previous agreement period. CMS created a Track 3 for ACOs in this rule that includes a prospective assignment methodology and a higher rate of shared savings. This new track differs from
Track 1 and 2 assignment methodology, which includes a preliminary prospective assignment with retrospective reconciliation.

Citing the failure of most ACOs to move to higher tracks that incorporate the risk of penalties, CMS released a final rule for the MSSP in December 2018 that seeks to accelerate ACOs’ transition to taking on downside risk. Under the new rule, beginning in July 2019, CMS will create two tracks, basic and enhanced. New ACOs would begin in the basic track and not have to bear risk for two years, as opposed to the current six-year period allowed before taking on risk. Current Track 1 ACOs would have one year to move to the enhanced, risk-bearing track. Organizations that represent ACOs and other stakeholders, including ASCRS in conjunction with the Alliance of Specialty Medicine, criticized the new structure when it was proposed, as it will likely force many Track 1 ACOs out of the program. The majority of current ACOs are Track 1, and if ophthalmologists do participate in ACOs, it is likely in Track 1.

Successful ASCRS ASOA Advocacy on Participation and Exclusivity

Although a previous final rule in the early years of the program was widely interpreted as allowing non-primary care physicians to practice in multiple ACOs, CMS applied exclusivity more broadly than it had indicated and precluded any practice that performs and bills evaluation and management (E/M) services from full-fledged participation in more than one ACO—regardless of specialty. Following reports from members, 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. As a result, on June 4, 2014, CMS released a final rule on Medicare Shared Savings Program ACOs, which allows ophthalmologists to participate as full-fledged participants in more than one ACO. Previously, the beneficiary assignment process would attribute a patient to an ACO based on whether he or she had seen a primary care physician in the ACO or whomever had billed the plurality of E/M services, which could have been an ophthalmologist. The attribution process would lock the physician into one ACO. In this rule, CMS excludes services provided by certain specialties, including ophthalmology, from the beneficiary assignment process, and thus excludes these specialties from being limited to full participation in one ACO. ASCRS commented to CMS expressing our support for this new attribution exclusion and prospective assignment option.

Despite our success in ensuring ophthalmologists may participate in more than one ACO, we were concerned that the 2018 ACO proposed rule may have had the unintended consequence of removing that ability in an attempt to allow beneficiaries to voluntarily designate their primary care provider, should a beneficiary select an ophthalmologist or another specialist as their primary care provider. To improve ACOs’ ability to identify attributed patients, the Bipartisan Budget Act of 2018 requires CMS to permit a Medicare FFS beneficiary to voluntarily identify an ACO professional as their primary care provider for purposes of assignment to an ACO. To meet the statute, CMS was considering modifying its current voluntary alignment policies to provide that it will assign a beneficiary to an ACO based upon his/her selection of any ACO professional, regardless of specialty, as their primary clinician. Specifically, a beneficiary would have been able to select a practitioner with any specialty designation, including ophthalmology, as their primary care provider and be eligible for assignment to the ACO in which the practitioner is an ACO professional, and locking that practitioner into one ACO. In our comments in conjunction with the Alliance of Specialty Medicine on the proposed rule, we opposed this potential opt-in. CMS noted that most commenters opposed its concepts for a beneficiary opt-in and stated in the final rule it will re-evaluate its potential opt-in policies and not move forward at this time.
New ACO Model Initiative
In March 2015, the U.S. Department of Health and Human Services announced the Next Generation ACO model of payment and care delivery, which emphasizes care coordination. The new model takes on greater performance risk and also potential share in a greater portion of savings.

CMS reports that the Next Generation ACO model offers ACOs a stable and predictable benchmark that they must meet to share savings and has tools that allow ACOs to have more of a relationship with their beneficiaries. For example, ACOs are able to reward beneficiaries for receiving their care from physicians and professionals participating in the ACOs. The model tests whether offering higher incentives for the care coordination activities that involve beneficiaries will lead to better health outcomes. CMS began accepting ACOs into this Next Generation ACO model through two rounds of applications in 2015 and 2016 and continues to seek applications. The Next Generation ACO model has been accepted as an Advanced APM for 2018, and CMS will likely also include it for the 2019 program year.

ACOs Under MACRA
MACRA includes two tracks for eligible professionals: remaining in traditional fee-for-service and participating in the MIPS program, or participating in Advanced APMs. Eligible professionals who receive a significant share of collective revenues through Advanced APMs that involve a risk of financial loss as well a quality measurement and an EHR component will receive 5% bonuses each year from 2019 to 2024.

CMS’ 2017 MACRA final rule, released in October 2016, detailed how physicians would be determined eligible for incentives for participating in Advanced APMs, such as ACOs. As noted above, only physicians participating in ACOs that involve two-sided risk, will be eligible for incentive payments. Track 1 ACOs do not qualify as advanced APMs. However, providers participating in those ACOs, known as MIPS APMs, will earn credit toward their MIPS scores.

Beginning in 2019, based on 2017 performance, physicians will receive a 5% bonus on Medicare Part B payments if their APM entities achieve collective payment or patient thresholds participating in advanced APMs. Thresholds for revenue and patient percentages increase each year and are listed below:

<table>
<thead>
<tr>
<th>Requirements for Incentive Payments for Significant Participation in Advanced APMs (Providers must meet payment or patient requirements.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Percentage of Payments through an Advanced APM</td>
</tr>
<tr>
<td>25%</td>
</tr>
<tr>
<td>Percentage of Patients through an Advanced APM</td>
</tr>
<tr>
<td>20%</td>
</tr>
</tbody>
</table>
MIPS Credit for ACOs (MIPS APMs)

Physicians participating in certain APMs that do not meet the requirements to be considered Advanced APMs, such as Track 1 ACOs, or do not meet the thresholds to receive the bonus payment for Advanced APMs will be scored under MIPS. CMS has developed a specific scoring standard for each of these MIPS APMs. For all MSSP ACOs, including Track 1, participants must report required quality measures for the ACO through the ACO entity, report data for the Promoting Interoperability category on their own, and will automatically receive at least half of the total available points for the Improvement Activities category score.

Similar to determining the thresholds for participation in Advanced APMs, CMS will award the same final MIPS score to all the participants in a MIPS APM entity, including for data they reported individually or as a group under a single TIN. Under the terms of the models considered MIPS APMs, participants in the APM entities are already assessed collectively for meeting certain quality and cost metrics; therefore, CMS will score the Promoting Interoperability and Improvement Activities categories collectively, as well. CMS will use an average score of all the participants’ scores for Advancing Care Information to determine a group score. All participants in the MIPS APMs will receive the same total available score for Improvement Activities. Please visit the ASCRS MACRA Center at ascrs.org/macracenter for full details on APMs.