Regulatory Relief UPDATE

ASCRS•ASOA is committed to advocating for regulatory relief to alleviate the financial and administrative burden federal programs place on our members' practices. ASCRS•ASOA has developed a robust list of recommendations and has been encouraged by recent initiatives from the Centers for Medicare & Medicaid Services (CMS) and Congress to provide regulatory relief to physicians from burdens associated with onerous program requirements.

The new administration has sought feedback on ways to reduce burden through several requests for information and incorporated many of our recommendations in recent proposed rules, including designating 2017 as a transition year for MACRA to allow physicians to easily avoid the MIPS penalty in 2019 and proposing to extend the transition through 2018. In addition, CMS proposes to modify the 2016 legacy quality reporting requirements to avoid a penalty in 2018.

In Congress, the House Ways and Means Health Subcommittee has launched a new initiative, known as the "Medicare Red Tape Relief Project," and is seeking feedback from physicians and other healthcare stakeholders on how Congress can help alleviate burden either through legislation or by working with CMS to modify regulations. ASCRS•ASOA provided feedback and expects the committee to begin considering strategies to reduce burden this fall. Additional ASCRS•ASOA recommendations include: extending the statutory authority of the Secretary of Health and Human Services (HHS) to continue the MACRA transition period and to set the Cost category of MIPS at a lower weight than the statutory requirement for an additional three years; ensuring robust Medicare Advantage (MA) provider networks that include ophthalmologists, especially sub-specialists, such as cornea, retina, or uveitis; limiting and streamlining MA plans' use of prior authorization and chart audits; and preserving physician and patient access to compounded drugs for office-use.

Regulatory Relief Wins to Date

Implementation of MACRA

2017 Quality Payment Program (QPP) Final Rule

- Secured a flexible performance period for the first MIPS transition year (2017) with the introduction of "pick your pace" and flexibility to avoid a 2019 penalty by reporting a minimal amount of data
- Lowered the Cost category score weight to 0% for 2017
- Reduced the quality reporting thresholds to 50% of eligible patients
- Reduced number of required measures in the Advancing Care Information category

2018 QPP Year 2 Proposed Rule

- Secured 2018 as another transition year
    - MIPS performance threshold increased slightly, but penalty avoided by submitting minimal data
    - Cost category score weight is held at 0% for 2018
- Increased the low-volume threshold to $90,000 in allowed Medicare Part B charges or 200 patients
- Secured the following for small practices of 15 or fewer:
    - 5-point MIPS bonus
    - Advancing Care Information Hardship exemption
    - Quality and Improvement Activities category scoring accommodations
- Allowed the continued use of 2014 Edition CEHRT
- Added bonus points in the scoring methodology for:
    - Caring for complex patients
    - Using 2015 Edition CEHRT exclusively

Other Regulatory Wins

2018 Medicare Physician Fee Schedule (MPFS) Proposed Rule

- Proposed to reduce the required PQRS measures reported in 2016 from 9 to 6 to avoid the 2018 penalty
- Proposed to reduce the penalty for the VBPM and not subject any physician who achieved PQRS to quality tiering

Drug Compounding

- In 2015, FDA released a draft guidance for repackaged drugs with an extremely short Beyond Use Date (BUD) that would have severely limited the use of Avastin. In 2017, following extensive advocacy by ASCRS and the ophthalmic community, the FDA released a revised draft guidance on repackaged drugs that reflected our recommendations to extend the BUDs for repackaged drugs if additional sterility testing was undertaken. This will ensure patients have continued access to repackaged Avastin.

Top Regulatory Relief "Asks"

- We are advocating for the following changes to MACRA:
    - Extending statutory authority for the Secretary of HHS to set the Resource Use, or "Cost" category of MIPS, at a lower weight than the statutory requirement of 30 percent, but no more than 10 percent, through the 2021 performance year.
    - Provide HHS Secretary with three additional years of flexibility through the 2021 performance year to continue setting the MIPS performance threshold at a level consistent with clinician readiness, rather than mean or median performance.
    - Clarify the definition of "small practice" to include only MIPS eligible clinicians.
    - Clarify that MIPS payment adjustments should apply only to covered professional services under the MPFS.
- In the 2018 MPFS final rule, we ask CMS to hold any physician who attempted to submit any data in 2016 harmless from the PQRS penalty. We also ask CMS to create an "administrative burden" hardship exemption for 2016 Meaningful Use.
- Curbing the use of chart audits by MA plans to ensure the plans are only conducting audits within CMS' requirements.
- Ensuring MA plan networks are robust and include enough specialists, and prohibiting plans from removing physicians from the network in the middle of the benefit year without cause.
- Streamlining and limiting the use of prior authorization by MA and Part D plans to ensure the requests are uniform and electronic.
- Lifting restrictions on the dissemination of off-label information to ensure open lines of communication between manufacturers and practitioners and modifying the Drug Quality and Security Act (DSQA) to allow physicians immediate access to obtain compounded medications for office-use from traditional 503A compounders in response to the FDA's RFI on regulatory relief.