Submissions to the Committee on Ways and Means, Subcommittee on Health
Regarding Statutory and Regulatory Burdens on Optimized Efficiency and Patient Care

Date:
Name of Submitting Organization:
American Society of Cataract and Refractive Surgery (ASCRS)

Address for Submitting Organization:
4000 Legato Rd. Ste. 700
Fairfax, VA 22033

Name of Submitting Staff:
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Statutory X  Regulatory X

Please describe the submitting organization’s interaction with the Medicare program:

The American Society of Cataract and Refractive Surgery (ASCRS) represents nearly 9,000 ophthalmologists who treat a high percentage of Medicare beneficiaries through traditional Part B Medicare fee-for-service and Medicare Advantage (MA) plans.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as “Appendix [insert label]”.

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Short Description:

2017 is the first performance year (to impact 2019 payments) of the Merit-Based Incentive Payment System (MIPS), created by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). While CMS has provided flexibility in the first year, and proposes to extend it for the second year, there are several statutory changes Congress should make, as well as provide oversight of CMS’ implementation of the program, to ensure ophthalmologists can participate fully and succeed in the program.

Summary:

• Physicians and practices need additional time to understand and implement the MIPS program.
MACRA is the biggest change to Medicare physician payments in decades, and thus will require the implementation of new administrative processes and clinical workflows. 2017 data does not have to be submitted until March of 2018, so practices—and CMS itself—will not have feedback on the program until well into the second performance year.

- The Cost category retains primary care-based measures that use an attribution methodology that potentially holds physicians responsible for care they did not provide, and CMS has yet to develop an appropriate risk-adjustment methodology. In addition, episode-based measures, such as cataract surgery, are not tested or well understood by physicians. While CMS has weighted the category at 0% for the first year, and proposes to do so again for the 2018 performance year, based on the MACRA statute, the weight will increase to 30% in 2019.

- Removing potentially topped-out measures may leave specialists without any relevant quality measures, and may mean high-volume procedures, such as cataract surgery, are not being measured by the MIPS program. Ophthalmologists had a high level of participation and achievement in the PQRS program, and continue to provide high-quality surgical care. Under CMS’ proposals, measures with high achievement could be removed from the program.

- Based on the MACRA statute, CMS is proposing to determine MIPS eligibility—and make payment adjustments—based on all items and services furnished under Part B. This could inaccurately determine physicians’ participation in Medicare, such as determining whether the physician falls under the low-volume threshold. In addition, this could limit patient access to Part B drugs administered in the office if the physician receives a MIPS penalty, and thus CMS must reduce the reimbursement payment on the drugs, as well. In future years of the program, the MIPS penalty could outpace the current average sales price plus the 6% payment physicians currently receive for administering these drugs in the office.

Related Statute/Regulation:

- The Medicare Access and CHIP Reauthorization Act of 2015 (P.L. 114-10)
- 2017 Quality Payment Program final rule
- 2018 Quality Payment Program proposed rule

Proposed Solution:

- Congress should amend the MACRA statute to provide for an additional three years of transition flexibility. The statute currently allows for two years, and without modification, would automatically require CMS to implement the program fully by setting the MIPS final score threshold at the mean or median of the previous year’s performance. Congress should delay the requirement to move to setting the MIPS final score using the previous year’s mean or median by three years, and allow for additional years of 0% weighting for the Cost category to allow for new episode-based measures that are relevant to the specialty to be developed. Congress should also give CMS additional flexibility in setting the weights of the other categories.

- Congress should provide oversight of CMS’ effort to develop episode-based measures to ensure the process is meeting the goals of improved attribution, risk adjustment, and reduced provider burden.

- Congress should amend MACRA to specify that the Secretary “may” remove certain topped out measures, rather than the current wording that the Secretary “shall.”
• Congress should amend MACRA to specify that MIPS eligibility and payment adjustments be based solely on physician services.
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Short Description:

Provide relief from penalties physicians face in 2018 based on reporting and performance under three programs: Electronic Health Record (EHR) Meaningful Use (MU), Physician Quality Reporting System (PQRS), and the Value-Based Payment Modifier (VBPM).

Summary:

- CMS is proposing in its 2018 Medicare Physician Payment Proposed Rule to provide relief by modifying the 2016 reporting requirements for PQRS and VBPM to allow more physicians to avoid the 2018 penalties. However, the proposals do not go far enough and do not include any relief from 2018 Meaningful Use penalties.
CMS currently proposes to reduce the required number of PQRS measures reported in 2016 to 6, down from 9.

CMS proposes to hold physicians who meet PQRS harmless from the VBPM penalty, and proposes to reduce the penalties by half (depending on practice size) for those not meeting PQRS.

- These programs are set to expire at the end of 2018 under provisions in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that streamlined burdensome and overlapping requirements for physicians under these programs.
- Physicians will need to invest time and resources as they transition to the new regulatory regime established under MACRA, further necessitating relief from penalties.
- Providing penalty relief for the pre-MACRA legacy programs will better align these with MACRA’s Quality Payment Program (QPP).

Related Statute/Regulation:

- CY 2018 Medicare Physician Fee Schedule final rule
- 2015–2017 Meaningful Use Modifications final rule
- CY 2018 Medicare Physician Fee Schedule proposed rule

Proposed Solution:

- **Meaningful Use** – We recommend Congress work with CMS to establish a new “Administrative Burden” category of hardship exemption for the 2016 MU performance year. Eligible providers should not be penalized for focusing on providing quality patient care rather than the arbitrary “check the box” requirements of MU.

- **PQRS** – We recommend that Congress work with CMS to reduce the reporting requirements for this program so that any physician who successfully reported on at least one PQRS measure in 2016 would avoid the 2% penalty in 2018. Physicians who did not successfully complete one measure in 2016 would be subject to the penalty.

- **VBPM** – We recommend Congress work with CMS to continue the current policy that any physician who avoided the PQRS penalty in 2018, including through the reduced reporting requirement requested above, would be exempt from any automatic VBPM penalties. Under the current program, physicians who are not successful in PQRS receive an automatic VBPM penalty. Under our recommendation, physicians who wanted to try for a bonus under the voluntary tiering system could do so but at their own risk. Therefore, a physician would only be penalized under the VPBM if he or she voluntarily chose to compete, and then scored poorly in the tiering process. It is important to retain this option since the statute requires that all physicians must be included in the VBPM by 2017—and there must be differential payment.
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Short Description:

FDA’s final guidance for 503A traditional compounders restricts Medicare beneficiaries’ access to compounded drugs administered in the physician’s office in emergent situations.

Summary:

- Ophthalmologists must have immediate access to small quantities of compounded drugs for office-use to provide treatment to patients presenting urgent conditions. Otherwise, a patient may experience extreme ocular damage or even complete blindness. For instance, if a patient presents with a pseudomonas aeruginosa corneal ulcer, which is a bacterium capable of perforating a cornea within 24 hours if untreated, compounded eye drops would
be the only means of effective treatment. Another example of an emergent condition would be bacterial endophthalmitis, an infection where bacteria has reached the inside of the eye, and if not treated within 24 hours with the injection of compounded antibiotics, a patient will almost certainly experience the loss of an eye. Therefore, it is imperative that physicians have access to compounded drugs for office-use to ensure timely and effective care of their patients.

- FDA’s draft guidance for 503A compounding pharmacies requires a patient-specific prescription for compounded medications. The Drug Quality and Security Act of 2012 (DSQA) created a new type of facility, 503B outsourcing facilities that are subject to FDA regulation and are permitted to compound without a patient-specific prescription.

- However, due the additional requirements, 503B outsourcing facilities have expressed their inability or lack of willingness to compound in the small quantities needed by many ophthalmologists to have on hand for emergent cases. Since drugs for emergent conditions are not used in ophthalmic practices on a regular basis, physicians generally order smaller quantities, which make it less cost-effective for the outsourcing facilities to produce. As a result, many outsourcing facilities do not produce in the requested quantities, thus limiting physician and patient access to these drugs. Attached in Appendix A to this submission is a list of ophthalmic drugs that a 503B outsourcing facility currently produces and a list of its products from 2013, prior to becoming an outsourcing facility.

- The DSQA includes a provision to require a patient-specific prescription for drugs obtained from a 503A traditional compounder; however, the co-sponsors of the legislation have repeatedly expressed that the intention of the law was not to interfere with drugs for office-use. The FDA has ignored those intentions, as well as comments from 503B outsourcing facilities, who note they cannot produce these drugs in the quantities needed, and maintains the patient-specific prescription for all drugs from 503A traditional compounders. Legislation has been introduced to remove the patient-specific prescription requirement.

Related Statute/Regulation:

- Prescription Requirement Under Section 503A (FDA Guidance for Industry)
- Drug Quality and Security Act of 2012 (PL 113-54)

Proposed Solution:

- Support H.R. 2871 to remove the patient-specific prescription requirement for 503A traditional compounders.

- Provide additional oversight of FDA’s regulation of compounded drugs.
Appendix A

LIST OF OPHTHALMIC DRUGS/INJECTABLES CURRENTLY BEING COMPOUNDED AT A FACILITY THAT IS NOW 503B

**Retina**
Bevacizumab
Brilliant Blue

**Cataract**
Cyclopentolate/Tropicamide/Phenylephrine
Lidocaine/Phenylephrine
Intravitreal Antibiotics:
  - Moxifloxacin
  - Cefuroxime
  - Vancomycin

**Lasik**
Mitomycin PF Solution

**Pediatric**
Atropine 0.01%
Cyclopentolate/Tropicamide/Phenylephrine (Diluted)

LIST OF OPHTHALMIC DRUGS/INJECTABLES BEING COMPOUNDED AVAILABLE IN 2013 BEFORE THE SAME FACILITY BECAME A 503B

**Anti Allergy Solutions**
Cromolyn 4% Preserved or Preservative Free Ophthalmic Solution $73.05/10ml
Naphazoline HCL Preservative Free Ophthalmic Solution $65.65/10ml
Naphazoline/Pheniramine Preservative Free Ophthalmic Solution $65.65/10ml
Pheniramine 0.3% PF Ophthalmic Solution $65.65/10ml
Zinc Sulfate 0.25% Preservative Free Ophthalmic Solution $50.85/10ml

**Anti-Infectives**

**Antibiotics**
Amikacin Ophthalmic Solution 10-50mg/ml $97.20/10ml
Azithromycin 2mg/ml PF Ophthalmic Solution $102.60/10ml
Azithromycin 1% PF Ophthalmic Solution $102.60/10ml
Bacitracin 400u/gm/Dexamethasone 0.05% Oph Ointment $63.20/4gm
Bacitracin Ophthalmic Solution 5,000 or 10,000 u/ml $53.30/10ml
Cefazolin Ophthalmic Suspension $77.95/10ml
Ceftazidime Ophthalmic Solution $82.90/10ml
Chloramphenicol 0.5% Preservative Free Ophthalmic Solution $82.90/10ml
Chloramphenicol 1.0% Ophthalmic Ointment $77.95/4gm
Chlorhexidine Ophthalmic Solution $63.20/10ml
Clindamycin Preservative Free Ophthalmic Suspension varies
Clindamycin 1% Ophthalmic Ointment varies
Clindamycin 0.3% Preservative Free Ophthalmic Solution $65.65/10ml
Clarithromycin 1% Ophthalmic Suspension $90.30/10ml
Doxycycline 0.025% or 0.1% Oph Solution $53.30/10ml
Fortified Cefazolin Ophthalmic Suspension $77.95/10ml
Fortified Gentamicin Ophthalmic Solution (also available Preservative Free) $64.40/7ml
Fortified Tobramycin Ophthalmic Solution (also available Preservative Free) $64.40/7ml
Fumidil B (bicyclohexyiammonium fumagillin) $103.10/10ml
Gentamicin Preservative Free 3mg/ml Oph Solution $53.30/5ml
Imipenem/Cil 5mg/ml Pf Oph Solution $102.60/10ml
Kanamycin Ophthalmic Solution 40mg/ml $44.15/10ml
Levofoxacin 5-25mg/ml Ophthalmic Solution $53.30/10ml
Metronidazole 0.5% Preserved or Preservative Free Ophthalmic Solution $66.15/10ml
Metronidazole 0.75% Ophthalmic ointment $68.10/4gm
Neomycin 15mg/ml Ophthalmic Suspension $41.00/10ml
Paromycin 15mg/ml Ophthalmic Solution $102.60/10ml
Penicillin G Potassium Ophthalmic Solution $83.40/10ml
Piperacillin 10mg/ml Pf Oph Solution $117.40/10ml
PHMB 0.01% or 0.02% $92.75/15ml
Polymyxin/Trimethoprim Preservative Free Ophthalmic Solution $102.60/10ml
Sodium Sulfacetamide 10%-30% Preservative Free Ophthalmic Solution $82.90/10ml
Sulfamethoxazole/Trimethoprim Ophthalmic Solution $65.65/10ml
Vancomycin 20mg/ml, 25mg/ml or 50mg/ml Ophthalmic Solution $77.95/10ml
Vancomycin 14mg/ml preservered (60 day exp date) $35/10ml
Tobramycin 0.3% /Dexamethasone 0.1% Oph Solution $65.65/5ml
Tobramycin 0.3% Preservative Free Oph Sol $77.95/10ml
Tetracycline 1% Preservative Free Oph Ointment $82.90/4gm

Anti-virals
Acyclovir 3% Ophthalmic Ointment $92.75/4gm
Cidofovir Ophthalmic Solution (Release is required) $225.85/3ml
Idoxuridine 1% or 0.1% Ophthalmic Solution $75.40/8ml
Idoxuridine 0.5% Ophthalmic Ointment $73.05/4gm
Trifluridine 1% Preservative Free Ophthalmic Solution $108.15/8ml
Trifluridine 0.5% Compounded Ophthalmic ointment $71.60/4gm
Vidarabine 3% Ophthalmic Ointment $92.35/4gm

Anti-fungals
Amphotericin 0.1-0.5% Ophthalmic Solution $77.35/10m
Clotrimazole 1% Ophthalmic Suspension $77.95/10ml
Fluconazole 2mg/ml Ophthalmic Solution $90.30/10ml
Flucytosine 10mg/ml Ophthalmic Solution $65.65/10ml
Itraconazole 1% Ophthalmic Suspension $78.95/10ml
Ketoconazole 5% Oph Suspension in Peanut oil $77.95/10ml
Micafungin 0.1% Oph Solution $144.25/5ml
Miconazole Nitrate 1% Ophthalmic Suspension $90.30/10ml
Natacyln Ophthalmic Suspension $231.52/15ml
Voriconazole 1% Cmpd Ophthalmic Solution $157.50/10ml

Cytotoxic Agents
Fluorouracil Ophthalmic Solution 1% $53.30/10ml
Thiotepa 1:2000/ 1:1000 Oph Solution $77.95/5ml
Mitomycin Injection or Ophthalmic Solution (all strengths) $45.52/1ml

Diagnostic Agents
Cocaine Ophthalmic Solution 4% & 10% Varies
Fluorescein Oph Solution 0.2% - 2% Preserved or Preservative Free $41.00/15ml
Glycerin 99.5% PF or Preserved Ophthalmic Suspension $32.06/10ml
Gonioscopic Gel (various strengths) $32.06/10ml
Hydroxyamphetamine 1% Preserved or PF 5ml $53.30/5ml
Lissamine Green 1% Preservative Free or Preserved Ophthalmic Solution $32.06/10ml
Rose Bengal Solution 1% Pres. Free or Preserved Ophthalmic Solution $41.00/10ml
Saccharin Sodium 10mg/ml $41.00/10ml
Sodium Saccharin 2% Ophthalmic Solution $41.00/10ml

**Dry Eye Compounds**
Albumin 5% Ophthalmic Solution $53.30/10ml
Aquasol A Ophthalmic Suspension $83.45/15ml
Calcium Carbonate 10% Ophthalmic Ointment $41.00/30gm
Castor Oil 2% Ophthalmic Suspension $32.06/10ml
Cyclosporine 0.2% Ophthalmic Ointment $62.65/4gm
Cyclosporine 0.05% in Cyclodextran Solution $83.35/10ml
Cyclosporine 0.05% /Dexamethasone 0.01 % in Cyclodextran Solution $90.30/10ml
Cyclosporine 0.05-2% Ophthalmic Suspension in Gum Cellulose varies
Dehydroepiandrosterone (DHEA) Ophthalmic Suspension 0.5% or 1% $90.30/10ml
Dextran Ophthalmic Suspension $32.06/10ml
 Estradiol 0.01-0.03% Ophthalmic Suspension $93.75/10ml
GumCellulose Preservative Free Ophthalmic Solution 0.3% to 2.5% $16.00/15ml
Hyaluronic Acid PF Ophthalmic Suspension 0.5% $144.55/10ml
Methylcellulose Preservative Free Ophthalmic Solution $16.00/15ml
Poly-Vinyl Alcohol/ Povidone Ophthalmic Solution $32.06/10ml
Rapeseed Oil 2% (Alpha Omega Drop) Suspension $32.06/10ml
Retinoic Acid (all trans) 0.01% Ophthalmic ointment $78.35/4gm
Retinoic Acid (all trans) 0.01% or 0.005% Ophthalmic Suspension $78.35/10ml
Serum Ophthalmic Drops varies
Sodium Carboxy Methylcellulose Ophthalmic Gel $16.00/15ml
Tacrolimus 0.02% Cmpd Ophthalmic Suspension $32.06/5 ml
Tacrolimus 0.02% Cmpd Ophthalmic Ointment $67.00/4 gm
Trehalose 3.78% Ophthalmic Solution $73.05/10ml
Vaseline Preservative Free Ophthalmic Ointment $78.55/4gm
Vitamin A 0.01% Oph Suspension (All Trans Retinoic Acid) $77.95/10ml
Vitamin A 0.01% Ophthalmic Ointment (All Trans Retinoic Acid) $78.35/4gm

**Glaucoma**
Acetazolamide 1% Preservative Free Ophthalmic Suspension $102.60/10ml
Apraclonidine Preservative Free** Ophthalmic Solution $77.95/5ml
Betaxolol 0.125% Preservative Free** Ophthalmic Solution $53.30/5ml
Bimatoprost 0.015% PF** Ophthalmic Solution $107.55/3ml
Brimonidine 0.1% or 0.075% Preservative Free** Ophthalmic Solution $102.60/10ml
Brinzolamide 0.5% PF** Ophthalmic Solution $45.95/5ml
Carbachol 1.5%, 2.25% & 3% Preservative Free Ophthalmic Solution $90.30/10ml
Clonidine Preserved or Preservative Free Ophthalmic Solution $65.65/10ml
Dipivefrin 0.1% Pres’d or Pf Oph Solution $55/5ml, $75.00/10ml
Dorzolamide 1% PF** Ophthalmic Drops $102.60/10ml
Dorzolamide 1%/Timolol 0.25% PF ** Ophthalmic Solution $97.2010ml
Epinephrine Bitartrate Preservative Free Ophthalmic Solution $74.35/10ml
Epinephrine Borate Preservative Free Ophthalmic Solution $97.20/10ml
Epinephrine HCL 1% Preserved Ophthalmic Solution $77.95/10ml
Latanoprost 0.0025% Preservative Free** Ophthalmic Solution $90.07/3ml
Levobutanol 0.25% PF** Ophthalmic Solution $53.30/5ml
Phospholine Iodide (all strengths) varies
Pilocarpine Preservative Free Ophthalmic Solutions 0.1% to 6% $65.65/10ml
Pilo 1%/Epi 1% Cmpd Ophthalmic Solution $41.00/5ml
Travoprost Z 0.002% Cmpd PF** Ophthalmic Suspension $83.35/3ml
Preservative Free Steroids
Dexamethasone Na Phos Injection 4-24mg/ml PF varies
Dexamethasone Sodium Phosphate Preservative Free Solutions $58.00/10ml
Dexamethasone 0.05% Ophthalmic Ointment $82.90/4gm
Dexamethasone 0.05% Lanolin Free Ophthalmic Ointment $82.90/4gm
Flurometholone 0.1% PF Ophthalmic Suspension $55.00/5ml
Loteprednol 0.25% PF** Ophthalmic Solution $74.35/ml
Methylprednisolone Na Succinate Preservative Free Ophthalmic Solution $77.95/10m
Prednisolone Acetate Preservative Free Ophthalmic Suspension $92.75/10ml
Prednisolone Sod Phos Preservative Free Ophthalmic Solution $82.90/10ml
Rimexolone 0.5% Cmpd PF ** Ophthalmic Solution $102.60/10ml
Triamcinolone 80mg/ml Preservative Free Compound Injection $20.00/1ml

Misc. Agents

Acetyl Cysteine 5-20% Ophthalmic Solution pf $77.95-97.70/10ml
Aminocaproic Acid 30% Ophthalmic Suspension $85.85/10m
Ascorbic Acid 10% Ophthalmic Suspension $87.85/10ml
Bevacizumab (Avastin) Cmpd Inj (various doses available) varies
Bevacizumab (Avastin) Topical Drops varies
Benoxinate 0.4% PF or Preserved Oph Solution $32.06/5ml
Boric Acid Ophthalmic Ointment $82.90/4gm
Brilliant Green 2% Ophthalinic Stain $32.06/10ml
Brilliant Blue G 0.25mg/1ml $10.00/1ml
Cysteamine 0.55% Cmpd Ophthalmic Solution $83.90/10ml
Diclofenac Sodium 0.1% Preservative Free Ophthalmic Solution $77.95/10ml
EDTA Preserved 0.4% to 3% varies
Ethanol (all concentrations) Ophthalmic Drops or Injectable $53.30/10ml
Indomethacin 0.5 or 1% Ophthalmic Suspension $92.75/15ml
Glutathione 6% Ophthalmic Solution $59.50/15ml
Glycerin 50% oral solution $55.60/220ml
Glycerin 50% Ophthalmic Solution $30.53/10ml
Guanethidine Preservative Free Ophthalmic Solution 2%, 5% or 7.5% varies
Heparin PF Ophthalmic Solution $32.06/10ml
Hyaluronidase Injection 150u/ml $15.00/1ml, $31.25/5 ml, $46.25 /10ml
Ibopamine 2% Ophthalmic Solution $65.00/5ml,$85.00/10ml
Interferon Alfa 2B Ophthalmic Solution (1-3mu/ml) $235.73/3-10ml (depends on strength)
Isosorbide 45% Cmpd Oral Solution $128.75/110ml
Medroxyprogesterone Acetate 0.5% or 1% Ophthalmic Suspension $40.91/10ml
PABA 10% Cmpd Ophthalmic Ointment $60.03/4gm
Phentolamine 0.083% Ophthalmic Solution $41.00/5ml
Physostigmine Salicylate 0.03%, 0.125% 0.25% or 0.5% Oph Solution $77.95/10ml
Physostigmine Salicylate Ophthalmic Ointment $87.85/4gm
Povidone-Iodine Ophthalmic Solution $53.30/10ml
Silver Nitrate Ophthalmic 0.5% or 1% Solution $53.30/10ml
Silver Protein 10% Ophthalmic Solution $44.15/10ml
Sodium Chloride 5% Ophthalmic Solution PF $53.30/10ml
Sodium Chloride 5% Preservative Free Ophthalmic Ointment $63.20/4gm
Sodium Citrate 10% Ophthalmic Solution $69.10/10ml
Tetrahydrolazine 0.05% PF Ophthalmic Solution $53.30/10ml
Vision Blue 0.06% Singles $52.00/each
Vitamin A 1%/ Vit C 1% /Glutathione 1%/DMSO 5% Ophthalmic Sol $98.70/10ml

**Topical Anesthetics, Reversal Agents and Combo Dilating Agents**

Atropine Sulfate Ophthalmic Solution 0.125% to 1% PF $50.90/10ml
Benoxinate 0.4% PF or Preserved Oph Solution $32.06/5ml
Cyclopentolate 0.5% to 1% P.F. $77.95/10ml
Cyclopentolate/Phenylephrine/Bupivicaine Combo Ophthalmic Solution varies
Cyclopentolate/Phenylephrine/Diclofenac Combo Ophthalmic Solution varies
Cyclopentolate/Phenylephrine Combo varies
Cyclopentolate/Proparacaine Combo varies
Dapiprazole 0.5% Topical Drops (compare to Rev-Eyes-Lyopholized) $40.00/6ml kit
Homatropine Preservative Free Ophthalmic Solution 5% $43.45/10ml
Lidocaine Ophthalmic Solution 0.5-0.4% $53.30/10ml
Phenylephrine Preservative Free Ophthalmic Solution 2.5% or 10% $53.30/10ml
Proparacaine Preserved or PF (0.03%, 0.05%, 0.1%, 0.25%) Ophthalmic Solution $43.35/10ml
Proparacaine 0.05% PH Adjusted Preserved Ophthalmic Solution $32.06/10ml
Proparacaine/Tropicamide/Cyclopentolate/Phenylephrine Combo Oph Sol varies
Scopolamine 0.25% Preservative Free Ophthalmic Solution $65.65/10ml
Tetracaine 0.5% PF Cmpd Ophthalmic Solution $32.06/5ml
Tetracaine 0.5% Ophthalmic Ointment $82.90/4gm
Tetracaine HCL 0.05% Preserved and Stabilized Oph Solution (Comfort Drops) $7.50/3 or 5ml
Tropicamide Preservative Free Ophthalmic Solution $53.30/10ml
Tropicamide 0.5%/Cyclopentolate 0.5%/PHN 2.5% Combo Spray $48.30/10ml
Tropicamide 1%/ Cyclopentolate 1% Ophthalmic Solution $53.30/10ml
Tropicamide 1%/ Phenylephrine 2.5% Preserved Ophthalmic Solution $53.30/10ml
Tropicamide 1%/ Phenylephrine 5% Preserved Ophthalmic Solution $53.30/10ml
Tropicamide 0.25%/ Phenylephrine 5% Preserved Ophthalmic Solution $53.30/10ml

**Tropicamide 1%/Cyclopentolate1%/Phenylephrine 2.5% Preserved Ophthalmic**
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Short Description:

Reduce burden on physician practices by limiting MA plan risk-adjustment chart audits.

Summary:

- Ophthalmology practices are frequently required to provide patient charts to MA plans undergoing risk-adjustment audits. In many cases, the requests are for one hundred or more charts with deadlines to comply in as little as a few days to a week. Pulling relevant patient charts and preparing them for submission is a labor-intensive activity, and small practices generally do not have enough staff to devote to complete the task in the required time.
• While we understand that these audits are for the MA plans themselves, and thus not punitive to the practices, they are an added burden to practices already facing many other regulatory requirements. MA plans must be able to provide a letter from CMS confirming the chart audit, but there is no standardization across plans to indicate how many, and in what time frame, the charts must be submitted.

• Many plans are unable or unwilling to provide proof of a CMS-initiated audit, and therefore, the requests may be in excess of what CMS actually requires of the plan.

• Sample chart requests from members are included in Appendix 1.

**Related Statute/Regulation:**

Annual MA call letters include parameters for the risk adjustment audits.

**Proposed Solution:**

• We recommend Congress work with CMS to ensure that MA plans undergoing risk-adjustment audits do not shift undue administrative burden to practices in their networks.
Submissions to the Committee on Ways and Means, Subcommittee on Health Regarding Statutory and Regulatory Burdens on Optimized Efficiency and Patient Care

Date: 
Name of Submitting Organization: American Society of Cataract and Refractive Surgery (ASCRS)

Address for Submitting Organization: 
4000 Legato Rd. Ste. 700 
Fairfax, VA 22033

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Statutory ___ Regulatory X

Please describe the submitting organization’s interaction with the Medicare program:

ASCRS represents nearly 9,000 ophthalmologists who treat a high percentage of Medicare beneficiaries through traditional Part B Medicare fee-for-service and Medicare Advantage (MA) plans.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

In the case of listed Appendices, please attach as PDF files at the end of the submission, clearly marked as “Appendix [insert label]”.

In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description:

MA plan narrow networks can disrupt ongoing patient care and restrict patient access to specialty, particular sub-specialty, care. Further limiting patient access, MA plans have dropped physicians from their networks in the middle of the benefit year with no opportunity to appeal. In addition, inaccurate MA plan directories cause beneficiaries to choose plans believing their physicians are included in the plan, when in fact, they are not.

Summary:

• We have heard frequently from practices that have been removed from MA plan networks in the middle of the benefit year, without cause, or that are not accurately listed in MA plan directories. These changes by MA plans risk worsening the condition of beneficiaries who are in stable condition under the care of a doctor whom they expected to be in-network. Ophthalmologists not only provide surgical care, such as for cataract surgery, but also...
provide ongoing care for chronic diseases, such as glaucoma and age-related macular degeneration. Patients with chronic eye disease need intensive, specialized, and uninterrupted care to prevent disease progression or complete blindness.

- In some cases, insurer efforts to narrow their networks have left plans without specialists who treat certain diseases. For example, we heard from some practices that were dropped from plans and are the only practices in their area with corneal or uveitis specialists. Often, sub-specialists treat the sickest and most complex patients. MA Plans that remove these sub-specialists from their networks are limiting access to beneficiaries who need the most care.

- Many practices complain that MA plan directories are inaccurate or incomplete. Without accurate provider directories, beneficiaries will not be able to choose plans that meet their needs.

- Frequently, when MA plans make network coverage decisions, they do so in the middle of the benefit year, without consulting the participating physicians, and do not provide any means of appealing or re-negotiating the decisions. Physicians have no opportunity to demonstrate how these decisions will affect their patient population or limit beneficiaries’ access to care.

Related Statute/Regulation:

2017 Medicare Advantage Call Letter

Proposed Solution:

- CMS has acted in the past to discourage plans from engaging in tactics to narrow networks in the middle of the benefit year, but we encourage Congress to work with CMS to prioritize ensuring that MA plan networks are robust enough to offer beneficiaries a choice of physicians, as well as the assurance that they will be able to use their MA benefits for the treatments they require.

- We recommend Congress work with CMS to ensure that all MA plans offer some options for out-of-network benefits to beneficiaries whose physicians may have been removed from the plan during the benefit year.

- We recommended Congress work with CMS to ensure MA plans keep provider directories up to date so that beneficiaries have assurance that they will be able to see the physician of their choice.

- Congress should work with CMS to ensure physicians have a clear and reliable method to repeal network participation decisions.
Submissions to the Committee on Ways and Means, Subcommittee on Health
Regarding Statutory and Regulatory Burdens on Optimized Efficiency and Patient Care

Date:

Name of Submitting Organization:
American Society of Cataract and Refractive Surgery (ASCRS)

Address for Submitting Organization:
4000 Legato Rd. Ste. 700
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Director of Government Relations

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703-591-2220

Submitting Staff E-mail:
nmccann@ascrs.org

Statutory ___ Regulatory ___

Please describe the submitting organization’s interaction with the Medicare program:

The American Society of Cataract and Refractive Surgery (ASCRS) represents nearly 9,000 ophthalmologists who treat a high percentage of Medicare beneficiaries through traditional Part B Medicare fee-for-service and Medicare Advantage (MA) plans.

Please use the below template as an example of a submission regarding statutory or regulatory concerns, and submit any further concerns past those listed below in a separate Microsoft Word document in the same format. Submissions must be in the requested format or they will not be considered.

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In the case of a multitude of submissions, it is recommended that they be submitted in order of priority for the submitting organization or individual.

Short Description:

Provide relief from private plans’ (including MA plans) use of prior authorization requests by requiring a streamlined and electronic process.

Summary:

• ASCRS recently partnered with the Alliance of Specialty Medicine (a coalition of 13 medical specialty organizations representing more than 100,000 specialty physicians) to survey our combined membership on regulatory burdens. Respondents consistently ranked the increased use of prior authorization by insurers as a top concern.
Over the last five years, physicians have seen a startling increase in the volume and breadth of prior authorization requests. The survey found that more than 85% of physicians are experiencing increased use of prior authorization by insurers. Ophthalmologists reported that brand name drugs and topical medications are the most likely to require prior authorization. In addition, a majority of members have had to delay treatment or avoid prescribing certain treatments due to prior authorization requests. Less than 3% of ophthalmologists reported having easy access to insurers’ medical directors, and an overwhelming majority believe the medical directors have no experience with ophthalmic services and drugs. Several respondents have reported hiring or designating full-time employees just to deal with prior authorization requests.

Specific ophthalmic responses related to prior authorization from the survey:

- “Often, we do not prescribe certain glaucoma drops due to known prior authorization difficulties, even if it is the most appropriate medicine for that patient. Also, often the ‘suggested/allowable’ medications are not in the same class drug, or are outdated due to documented adverse side effects or have an allergy component to them that we would never prescribe to anyone.”
- “I try to write for all generics whenever possible. I have had difficulty with severe glaucoma patients obtaining the medications they need.”
- “Dry eye and allergic conjunctivitis treatments have become particularly time consuming to get approval.”
- “Insurance will give preauthorization and then deny they gave it.”

Each insurer tends to have its own policies and procedures for physicians to respond to the requests. Some have electronic portals; others require faxed responses.

These initiatives are burdensome and disruptive to physician practices, and they ultimately delay or deny care to Medicare beneficiaries.

Related Statute/Regulation:

Proposed Solution:

- Congress should work with CMS to streamline the prior authorization process used by Medicare Advantage and Part D plans by requiring standardized forms and electronic transactions.

- We encourage sparing use of prior authorization to ensure timely delivery of standard, evidence-based treatment for given conditions that is not based solely on cost criteria.

- We encourage processes that allow for true “peer-to-peer” dialogues. Specialists seeking prior authorization for pharmaceutical therapy on behalf of a patient should be routed to a specialist in the same or similar discipline with expertise in the given condition to discuss the request—not a pharmacist who is unfamiliar with disease processes and care management.