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August 31, 2017

Ms. Seema Verma
Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1676-P; Request for Information regarding Efficiencies and Flexibilities in the Medicare Physician Fee Schedule.

Dear Administrator Verma:

These comments are submitted by the American Academy of Ophthalmology in response to the Request for Information regarding Efficiencies and Flexibilities in the Medicare Physician Fee Schedule as part of the Notice of Proposed Rulemaking for the 2018 Medicare Physician Fee Schedule as published by CMS on July 13, 2017. The American Academy of Ophthalmology is the largest association of eye physicians and surgeons in the United States. A nationwide community of nearly 20,000 medical doctors, we protect sight and empower lives by setting the standards for ophthalmic education and advocating for our patients and the public. We innovate to advance our profession and to ensure the delivery of the highest-quality eye care.

The Academy was pleased to have participated in Secretary Price's recent Roundtable on Regulatory Relief. We greatly appreciate that CMS moved quickly and proposed substantial relief from the burdens and penalties of the existing legacy PQRS and Value-based Modifier programs for 2018. Specific comments on those issues as well as other MPFS coding and valuation issues are submitted in a separate comment letter.

Provided below are the list of items that we believe CMS and HHS should review in order to relieve the significant administrative burdens faced by ophthalmologists and other providers under Medicare and Medicare Advantage. There are many flexibilities and efficiencies that CMS should consider simplifying that would improve the Medicare program for providers and beneficiaries.

We will address the following areas:

- MACRA Bonus and Penalties on Part B Drug Payments
- Incentivizing QCDR Use via ACI
- Incentivizing the use of QCDR Through MIPS Bonus Payments
- Topped Out Measures Under MIPS
- Resource Use Category Under MIPS
- MACRA Mean Median Threshold
- Prior authorization simplification under Medicare Advantage

➢ MACRA Bonus and Penalties on Part B Drug Payments

Under the new Merit-Based Incentive Payment System (MIPS), clinicians will receive either a positive, neutral, or negative adjustment to their Medicare payments depending on their performance in the program. Payment adjustments are budget neutral and are set at plus or minus 4% in 2019 and rise to plus or minus 9% from 2022 onward. (There is also an additional bonus payment of $500M for exceptionally high performers from 2019-2024 that is not budget neutral).

In the 2018 Quality Payment Program (QPP) Proposed Rule, CMS clarifies that when a MIPS clinician furnishes and bills for Part B drugs, the payment adjustments (both positive and negative) will apply to the Part B drug payment. Since the physician will have knowledge of their payment modifier, this produces the potential perverse incentive. If physicians know they will be penalized, this could result in access problems for patients needing expensive drugs. On the other hand, for physicians receiving the bonus, there would be a potential for a substantial bonus' if they prescribe/treat patients with expensive Part B drugs.

Related Statute/Regulation:

This is a significant departure from current CMS' policy for applying payment adjustments for other programs like PQRS, meaningful use, and the value-based modifier. These programs applied payment adjustments to services under the Medicare Physician Fee Schedule, but did not apply them to Part B drugs. However, the MACRA statute appears to require that CMS apply the adjustment to all Part B "items and services," including drugs.

TITLE I--SGR REPEAL AND MEDICARE PROVIDER PAYMENT MODERNIZATION

SEC. 101. REPEALING THE SUSTAINABLE GROWTH RATE (SGR)
AND IMPROVING MEDICARE PAYMENT FOR PHYSICIANS' SERVICES.

(c)

''(7) ANNOUNCEMENT OF RESULT OF ADJUSTMENTS.—Under the MIPS, the Secretary shall, not later than 30 days prior to January 1 of the year involved, make available to MIPS eligible professionals the MIPS adjustment

factor (and, as applicable, the additional MIPS adjustment factor) under paragraph (6) applicable to the eligible professional for items and services furnished by the professional for such year. The Secretary may include such information in the confidential feedback under paragraph (12)."

Proposed Solution:

CMS should discuss with Congress the need to clarify its interpretation or make a technical correction that bonus and penalty payments should not be applied to Part B Drug Payments to physicians.

➢CMS should incentivize use of QCDRs through MIPS

MACRA includes a number of provisions reflecting Congress' intent that the new physician payment system was intended to incentivize the use of Qualified Clinical Data Registries (QCDRs). CMS has implemented regulations consistent with Congressional intent in a number of respects, including provisions that authorize QCDRs to submit data not only for the Quality and Improvement Activity components of MIPS, but also for the Advancing Care Information (ACI)/ Meaningful Use (MU) performance category. Unfortunately, while the MIPS regulations streamline the ACI/MU requirements, no changes were made to the underlying focus of the measures, which are not relevant to many clinicians and do not improve quality of care for patients. **ACI remains overly complex, burdensome and not achievable for many physicians. This program remains discouraging to doctors and contributing to physician burnout.**

Under current regulations, CMS will award clinicians 5 bonus points *per* QCDR under the ACI//MU component of MIPS. This amounts to only 1.25 points on the composite score, as most specialists have only one QCDR available. Providing full credit under the ACI/MU component of MIPS for physicians who use their certified EHR Technology (CEHRT) to participate in a clinician led QCDR would provide a significant incentive for physicians and other MIPS-eligible professionals (EPs) to utilize an EHR and participate in a specialty led QCDR with proven quality and patient outcome improvements. Outside of certain interoperability and security requirements, the definition of meaningful use of CEHRT is largely at the discretion of the Secretary.

Under MACRA (Sec. 101 (c)(1), adding Section, new §1848 (q)(1)(E) of the Social Security Act)) CMS is supposed to incentivize QCDR and EHR reporting of quality measures.

> `(E) Use of registries.--Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection."

The Social Security Act (Section 1848(q) (5)(B)(ii)(II)) specifically provides that a MIPS eligible physician who reports quality measures through CEHRT is entitled to be treated as meeting ACI/MU requirements with regard to electronic reporting of quality measures. However, the statute does not specifically require the Secretary to consider a physician who uses CEHRT to participate in a QCDR to be considered to be in compliance with other ACI/MU requirements (i.e. MU definitional requirements or interoperability-related requirements) that must be met for a physician to obtain full credit under the ACI/MU component of MIPS. Relevant provisions of the Social Security Act related to the definition of "Meaningful EHR User" provide the Secretary with broad regulatory authority to define these other ACI/MU requirements. See Social Security Act, Section 1848(o)(2)(A)(i):

> (2) Meaningful EHR User
> (A) An eligible professional shall be treated as a meaningful EHR user for an EHR reporting period for a payment year . . .if each of the following requirements are met:
>
> (i) MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—The eligible professional demonstrates to the satisfaction of the Secretary,. . ., that during such period the professional is using certified EHR technology in a meaningful manner, **which shall include the use of electronic prescribing <u>as determined to be appropriate by the Secretary</u>**.
> (Emphasis added).

Proposed Solution:

Active engagement in a specialty QCDR should count for the entire ACI/MU Category, providing 25 points on the composite score based on the current weighting. In addition, these eligible clinicians should receive at least 50 percent credit towards their Quality Category composite score. A regulatory approach would involve modifying the MACRA regulations that address the requirements that must be met for a physician to receive full credit for the ACI/MU component and partial credit for the Quality Component of MIPS 42 CFR § 414.1375 (ACI/MU Category requirements); 42 CFR § 414.1330-414.1340 (Quality Category Requirements); and 42 CFR § 414.1380 (scoring).

See attached **Appendix Final Registry ACI Credit Sign On Letter 6-20-17.**

➢ Incentivizing the use of QCDR Through MIPS Bonus Payments

MACRA includes a number of provisions reflecting Congress' intent that the new physician payment system was to incentivize the use of Qualified Clinical Data Registries (QCDRs). CMS' implementing regulations are

consistent with congressional intent in a number of respects, including in particular provisions that authorize QCDRs to submit data not only for the Quality and Clinical Practice Improvement Activity (CPIA) components of MIPS, but also for the Advancing Care Information (ACI)/ Meaningful Use (MU) performance category. Unfortunately, while the MIPS regulations significantly streamline many requirements compared to legacy programs such as MU and PQRS, QCDR participation using CEHRT is generally not incentivized to a level that recognizes the contribution of such participation to quality and patient outcomes.

Because of its contributions across all components of QPP, Congress and CMS should consider an overall bonus for any Eligible Professional (EP) who uses CEHRT to participate in a QCDR, along the lines of the 5% bonus provided for those who successfully participate in Patient Centered Medical Homes and Alternative Payment Models. At a minimum, MACRA should be amended to provide for bonus points to be added to the MIPS composite score of an EP who uses CEHRT to participate in a QCDR.

Related Statute/Regulation:

Under MACRA (Sec. 101 (c)(1), adding new Social Security Act (SSA) §1848 (q)(1)(E)), CMS is supposed to incentivize QCDR participation and EHR reporting of quality measures.

> " (E) Use of registries.--Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection."

See also SSA § 1848(q) (5) (B) (ii) (encouraging use of QCDRs and certified EHR technology). .

The statutory provision that provides for a 5% incentive payment for an EP who meets APM thresholds was added by MACRA at the end of SSA §1833(42 U.S.C. 1395l) as new subsection (z)(1), and could be used as a model for a new bonus payment for a MIPS EP who uses CEHRT to participate in a QCDR.

At a minimum, the provisions of SSA §1848(q)(5), relating the calculation of MIPS composite performance scores, should be modified to include bonus points for EPs who use CEHRT for participation in a QCDR.

Proposed Solution:

- Specialty led registry participation is a more meaningful tool with proven impact on quality of care and patient outcomes. QCDR participation incentives similar to those provided for participation in Patient-Centered Medical Homes and Alternative Payment Models should be a top priority under QPP.

- The governing legislation could be amended to provide EPs a bonus similar to that provided to those EPs with substantial participation in

a medical home to achieve APM, if they use CEHRT to participate in a QCDR.

- As the alternative, CMS could award 10-15 overall points on an EP's composite score for participation in a QCDR through CEHRT.

➢Topped Out Measures Under MIPS

The MACRA statute calls for CMS to publish an updated list of quality measures every year, including "removing from such list, as appropriate, quality measures, which may include the removal of measures that are no longer meaningful (such as measures that are topped out)". [emphasis added] CMS is proposing to remove all measures that with an average performance rate at or above 95%, three years after their identification, regardless of the availability of measures to replace them. This is highly problematic for the following reasons:

- Many topped out quality measures are still highly meaningful and are important to continue to monitor. Anything less than continued very high performance, or a lapse in performance, on these measures is concerning and should be flagged.
    - For instance, certain surgical and procedural complications should occur only rarely, a rate that exceeds 4 percent should be a red flag.
    - This rate falls within the topped out range, but is vitally important to measure and monitor in clinical practice.
    - Once topped out measures are removed from reporting, performance declines.[1]
- The new measure approval process takes a minimum of 2 years after the measure is developed. Arbitrarily removing all measures that are labelled "topped out" will leave most specialists without the minimum 6 measures needed to fulfill the quality component.
    - Many high-performing specialties and subspecialties have topped out their quality measures
    - This will require specialists and subspecialists to report on measures that are not at all meaningful to their specialty/patient population (i.e. primary care measures).
    - CMS limits QCDR measures to a maximum of 30 measures per clinical data registry limiting the number of measures available for some subspecialists.

Related Statute/Regulation:

[1] Lester Helen, Schmittdiel Julie, Selby Joe, FiremanBruce, Campbell Stephen, Lee Janelle et al. The impact of removing financial incentives from clinical quality indicators: longitudinal analysis of four Kaiser Permanente indicators BMJ 2010; 340 :c1898

MACRA:

"(II) not later than November 1 of the year prior to the first day of each subsequent performance period, update the final list of quality measures from the previous year (and publish such updated final list in the Federal Register), by—

"(aa) removing from such list, as appropriate, quality measures, which may include the removal of measures that are no longer meaningful (such as measures that are topped out);"

MACRA (Sec. 101 (c)(4)(B)(ii)) directs CMS to incentivize QCDR and EHR quality submissions:

- `(E) Use of registries.--Under the MIPS, the Secretary shall encourage the use of qualified clinical data registries pursuant to subsection (m)(3)(E) in carrying out this subsection."

The Quality Payment Program 2018 NPRM proposes to phase out topped out measures within 3 years of identification, regardless of availability of new measures for the specialty or subspecialty.

Proposed Solution:

- CMS is not required to remove all topped out measures from MIPS and this should be clarified via the rulemaking process and the current provisions revised.
- CMS should follow the spirit of the law and not restrict QCDRs from developing more relevant and meaningful quality measures for physicians by limiting registries to 30 QCDR measures.

➢ Cost/Resource Use Category Under MIPS

We appreciate that CMS recognized the need to revamp the legacy Value-based Modifier measures and attribution of clinician costs by allowing flexibility in the weighting of the Cost Category for the 2017 and 2018 performance years under MIPS. Given the current state of Cost measure development, however, the statutory requirement to increase Cost weight to 30% beginning in 2019 is likely to rush the development of Cost measures, causing MIPS to exhibit the same issues in resource use measurement as the legacy programs.

- As CMS continues to work on replacing the flawed cost? measures under the Value Modifier, additional flexibility would allow us to avoid rushing and to develop a complete set of care episode measures prior to implementation, in contrast to the handful of measures that are being developed currently.
- The care episode measures still under development, while appear to be an improvement, are not ready for beta testing, let alone implementation.

- We are concerned that rushing this process will lead to another flawed resource use measurement program, that we experienced under the value-based modifier.

Related Statute/Regulation:

MACRA/Section 1848(q)(2)(E)(i)(II) of the Social Security Act:

"(II) RESOURCE USE.—

"(aa) IN GENERAL.—Subject to item (bb), thirty percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A).

"(bb) FIRST 2 YEARS.—For the first year for which the MIPS applies to payments, not more than 10 percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A). For the second year for which the MIPS applies to payments, not more than 15 percent of such score shall be based on performance with respect to the category described in clause (ii) of paragraph (2)(A)."

Proposed Solution:

- We ask, given the current stage in measure development and the time needed to ensure a more accurate and successful implementation, that Secretary Price seek continued flexibility from Congress, similar to the first two years of MIPS, to further delay the implementation of the Cost Category under MACRA for at least two to three more years.
- Alternatively, if Congress acts to limit Cost weighted at 10% of the MIPS Final Score during the 2019 Performance Year, instead of the scheduled 30%, that percentage would somewhat limit the impact while allowing time for further development of Cost measures and a paced transition to the implementation of these new measures.

➢ MACRA Mean Median Threshold

In MACRA, there is a statutory provision that requires a mean/median approach to determining a performance threshold beginning in the 2019 performance year. This is likely to be problematic for the following reasons:

- Current requirement may result in 50% of physicians receiving a penalty, when many of those are providing good quality care.
    - If the mean and median scores are high, the mean/median threshold will have the effect of curving performance scores downward – causing high quality clinicians to appear low quality and to be penalized.

- CMS is unable to score clinician performance in real time. Often, scores are not received for a year or more after the performance data is collected. Given this delay, it is likely that physicians will not know how they are performing and whether they are on a successful path.
- Finally, significant revisions to the QPP are still being made and the Cost Category is being refined. Implementation of the mean/median scoring method during this time may create difficulty in ensuring penalties are levied appropriately.

Related Statute/Regulation:

MACRA/Section 1848(q)(6)(D)(iii):

> ``(iii) Special rule for initial 2 years.--
> With respect to each of the first two years to which the MIPS applies, the Secretary shall, prior to the performance period for such years, establish a performance threshold for purposes of determining MIPS adjustment factors under subparagraph (A) and a threshold for purposes of determining additional MIPS adjustment factors under subparagraph (C). Each such performance threshold shall--
> ``(I) be based on a period prior to such performance periods; and
> ``(II) take into account--
> ``(aa) data available with respect to performance on measures and activities that may be used under the performance categories under subparagraph (2)(B); and
> ``(bb) other factors determined appropriate by the Secretary.

Proposed Solution:

We recommend that Congress modify the language in Section 1848(q)(6)(D)(iii) from the "first two years" to "five years" and Congress further clarify that the threshold does not have to be a mean or median. We recommend that the Secretary create a middle, neutral range of 20 percent where practitioners would not be penalized or receive the bonus.

➢ Prior authorization simplification under Medicare Advantage

In recent years, the proportion of Medicare-eligible patients enrolled in Medicare Advantage Organizations (MAOs) plans has grown significantly: MAOs now cover almost 18 million people –- nearly one-third of all Medicare beneficiaries. In spite of payment reductions enacted in the

Affordable Care Act, federal payments to MAOs for 2014 were estimated to be 2 percent higher than traditional Medicare spending, on average.[2] Yet, over the past several years, these plans have imposed increasingly onerous prior authorization (PA) requirements for medical procedures, services and drugs-PA requirements that are not applicable under fee for service Medicare.

The growing burden of PA requirements increases provider costs and imposes significant hardship on Medicare patients seeking access to medically necessary services. The list of procedures and services subject to prior notification or PA is growing and varies based on the MA plan involved. For example, Humana has recently published a prior authorization/notification list that includes a number of new procedures and services.[3] The PA website for United Healthcare is 16 pages long and includes multiple lists of services and procedures applicable to different United plans.[4] A 2009 study published in *Health Affairs* indicates that, when time is converted to dollars, the national time cost to practices of interactions with plans is at least $23 billion to $31 billion each year.[5]

Moreover, the most recent Medicare audit of MA plans the 2016 Part C and Part D Program Audit and Enforcement Report prepared by the Medicare Parts C and D Oversight and Enforcement Group Date: May 9, 2017 (the "Audit Report") https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2016_Program_Audit_Enforcement_Report.pdf. indicates that MA plans in fact frequently violate Medicare rules related to PA timelines and other requirements and that these problems have persisted for many years.

And while PA determinations are binding on all "parties" unless appealed (42 CFR Sections §422.576), MAOs are not considered "parties" and no regulation of which we are aware binds a MA plan to provide coverage even if it has granted prior approval. We are aware that, in some cases, coverage is subsequently denied even if PA has been obtained.

We believe prior authorization is a challenge that needs to be addressed through a multifaceted approach to reduce burdens on physicians and ensure timely access to health care services for patients, as described in greater detail below.

The Medicare statute expressly requires that MA plans "provide to members enrolled under [Medicare Advantage] . . . benefits under the original Medicare fee-for-service program option," Social Security Act

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[2] http://kff.org/medicare/issue-brief/medicare-advantage-plans-in-2017-short-term-outlook-is-stable/.
[3] http://apps.humana.com/marketing/documents.asp?file=3063424.
[4] https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/UnitedHealthcare_Medicare_Solutions_Advance_Notification_List.pdf.
[5] http://content.healthaffairs.org/content/28/4/w533.abstract.

(SSA) § 1852(a)(1)(A),(B) (emphasis added); see also 42 C.F.R. §§ 417.414(b) and 422.101(a) and (b) (requiring all Section 1876 cost plans and MAOs to "provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare). Implementation of these authorities with respect to prior authorization and step therapy appears to be internally inconsistent: While a September 12, 2012 memorandum from CMS to MAOs suggests that pre-service requirements (in that case, step therapy requirements) may be imposed by MAOs only to the extent that such restrictions are implemented under FFS Medicare, the Medicare regulations require MAOs to make "standard" organization determinations within 14 days extendable for an additional 14 days) and expedited determinations within 72 hours. See, e.g. (42 CFR § 422.568), and these timelines have been applied to PA requests. Applicable provisions of the Medicare Managed Care Manual (Chapter 13, Section 31, 70.1, 70.7) explicitly recognize that MAOs routinely require PA ("pre-service" determinations).

Proposed Solution: We believe that a multi-faceted approach to this issue is needed:

- The Medicare statute/regulations should be revised:
  - To clarify that PA determinations are binding on MAOs and that a MAO may not deny subsequently deny coverage for any reason other than fraud or misrepresentation of the facts.
  - To provide that determinations on PA requests for items or services covered under Part B made on an expedited basis be made within 24 hours after receiving the request or no later than 48 hours in the case of a standard request, and that Part D plans make any such determination no later than 24 hours after receiving the PA request for expedited cases, or no later than 72 hours after receiving the request for standard cases.

- Medicare administrative audit and oversight practices should be modified to:
  - Include audit of MAO PA practices in all routine and special reviews of MAOs conducted by CMS and consider expanding RAC authority to include MAO PA practices.
  - Require MAOs to post their deficiencies with regard to the processing of PA requests prominently on their websites.
  - Require any MAO that is in repeated violation of these requirements to provide a specific corrective action plan and could request the agency to follow up to ensure that the corrective action plan has been implemented.
  - Require MAOs in repeated violation of regulatory requirements establish and publicize a physician PA hotline and to share access to the hotline with CMS auditors.

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Conclusion

We appreciate the opportunity to comment on Medicare efficiencies and flexibility needed for our members under Medicare and Medicare Advantage. If you have questions or need any additional information regarding any portion of these comments, please contact Ms. Cherie McNett, AAO Health Policy Director at cmcnett@aao.org or via phone at 202-737-6662. Again, the Academy would like to thank you for providing us with the opportunity to comment and to work with CMS to make the adjustments as requested.

Sincerely,

Michael X. Repka, M.D., M.B.A.
AAO Medical Director for Government Affairs