



Sound Policy. Quality Care.

January 16, 2018

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Submitted electronically via Regulations.gov

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Program, and the PACE Program

Dear Administrator Verma,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from 13 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

Today, the undersigned member organizations of the Alliance write to provide feedback on various proposals that impact specialty physicians and the patients we serve. We look forward to working with you and the agency as you work toward improving access to specialty medicine for the millions of beneficiaries enrolled in Medicare Advantage (MA) and Part D Prescription Drug Programs.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

We appreciate that CMS is soliciting feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. The agency has expressed particular interest in receiving stakeholder feedback on key topics, including:

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.
- Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.
- Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.
- Including survey measures of physicians' experiences.

Specialty physicians face significant challenges interacting with MA plans, especially when it comes to network adequacy. MA plans, especially those that have fallen short of a 5-star rating in recent years, have narrowed their provider networks to the point of eliminating some specialties and subspecialties altogether, which creates significant access to care challenges for patients with chronic health conditions appropriately diagnosed, treated, and managed by specialty medical professionals.

We believe there are multiple opportunities to leverage the Quality Rating System to improve enrollee access to specialty medicine, as well as more accurately differentiate plans based on the quality of specialty providers and the care they deliver. Moreover, we believe the below suggested stars measures adhere to CMS' guiding principles.

Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans. Specialty and subspecialty physicians that participate in CMS' Quality Payment Program (QPP), through the Merit-based Incentive Payment System (MIPS) or Advanced Alternative Payment Models (AAPMs), help to support and improve MA performance under the Quality Rating System. To that end, **we urge CMS to establish a stars measure that would award points to MA plans that maintain an adequate network of physicians who participate in the QPP.** This would incentivize MA plans to retain specialty and subspecialty physicians as "in-network" when they can demonstrate their broad contributions to improved quality and resource use. The weight for this measure should be at least 1.5.

Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics. As noted above, narrow networks impact beneficiary access to high-quality specialty medical care. Specialty and subspecialty physicians continue to be eliminated from MA plans, frequently in the middle of a plan year, leaving beneficiaries with limited or no access to care for chronic health conditions, such as glaucoma, macular degeneration, rheumatoid arthritis, lupus, and skin cancer, which are best managed by specialists with expertise in those disease areas. When a plan does not have an adequate network of specialty and subspecialty providers, it is impossible for beneficiaries to access the full range of providers and treatments they may need, thus diminishing quality and outcomes. Oftentimes, enrollees may not realize they need specialty medical care until after they have enrolled in a plan and new symptoms present or an existing condition worsens. To that end, **we urge CMS to include a stars measure that would award points to MA plans that maintain an adequate network of specialty and subspecialty physicians.** The weight for this measure should be at least 3.0.

To accomplish this, **CMS must require MA plans to accurately identify physician specialties and subspecialties when calculating network adequacy using the Healthcare Provider Taxonomy code set,** which was developed by the National Uniform Claims Committee (NUCC) to distinguish between specialty and subspecialty physicians. These codes are already employed by physicians when applying for a National Provider Identifier (NPI) through the National Plan and Provider Enumeration System (NPPES).

Including survey measures of physicians' experiences. **We strongly support development of a survey of physicians experiences with MA plans and encourage CMS to collaborate with the Alliance to develop a domain of questions focused specialty physician issues.** Questions should focus on network adequacy, including the accuracy of provider directories and provider termination practices, as well as payment and reimbursement practices, including sufficiency of payment rates, volume of denials, denials following prior authorizations, and other tactics that deny or slow payment after services are rendered.

In addition, questions should address MA audits, including those that are CMS-initiated and those that are conducted by the MA plan for other purposes.

Finally, questions should focus on issues that impede access to specialty medical care and treatment, including prior authorization practices, step-therapy requirements, non-medical switching of medications, and other administrative barriers that inappropriately diminish or slow beneficiary access to medically necessary diagnostic and therapeutic services and treatment. These issues are of particular concern to specialty physicians, and prompted a 2016 survey of Alliance member organizations to understand the breadth and depth of these issues on practices and patients. The results were profound (see Appendix A). More than 1,000 specialists responded and pointed to these administrative challenges, including prior authorizations, as a key driver of delays in access to life-saving, life-altering care and treatment for their patients. In fact, one respondent commented, *“Never have I spent more time on administrative issues that do nothing but delay appropriate diagnostic and therapeutic intervention.”* Another respondent said, *“I have patients that have been hospitalized and almost died due to the delays imposed by prior authorizations and inexperienced unknowledgeable ‘physicians’...making decisions on complex rheumatologic treatments being given to seriously ill rheumatology patients – this is shameful, if not criminal.”*

Unfortunately, specialists have little recourse with insurers in addressing these challenges. One respondent explained, *“I take all insurances basically to improve access of care [in] my area even at personal losses. I am not sure how much longer we can do this.”*

Toward that end, ***we urge CMS to establish a stars measure that would award points to MA plans based on physicians experiences with MA plans.*** We believe this will incentivize plans to reduce excessive barriers to care in line with CMS’ “Patients Over Paperwork” initiative. The weight for this measure should be at least 3.0.

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

When the Part D program was established, CMS believed that establishing a minimum threshold for price concessions to be applied at the point of sale would undercut competition. However, in recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale. Plan sponsors and their pharmacy benefit managers (PBMs) may have distorted incentives as compared to what CMS intended in 2005. In fact, CMS data indicates that the current construct raises costs for both beneficiaries and the program and may undermine the competitive bidding process of the program. Certainly, this data supports what physicians are seeing in their practices. In recent years, prescribers have seen the out-of-pocket obligations for patients rise at unsustainable rates, even as patients’ ability to access medication is hamstrung by ever-increasing utilization management techniques. In its Request for Information (RFI), CMS solicits comment on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug’s negotiated price at the point of sale.

CMS provides ten-year impact estimates of a forced pass-through of 33%, 66%, 90%, and 100% of manufacturer rebates at the point of sale: at the lowest point of that range (33%), beneficiaries would save \$19.6 billion dollars in their out-of-pocket costs. Requiring that all pharmacy price concessions be used to lower the price at the point of sale would similarly affect beneficiaries and the program. While a

pass-through policy would increase premiums, that increase is more than offset by the deep reductions in cost-sharing at every level of pass-through. Indeed, any argument that the policy would increase premiums is disingenuous as it does not factor in the offsetting impact of the large reductions in cost-sharing. As prescribers, we have seen firsthand how rising out-of-pocket costs negatively affect adherence. Patients will ration their medications, or simply not fill their needed prescriptions altogether. As such, ***we strongly support a mandatory pass-through of price concessions and urge the agency to move forward with implementing such a policy.***

“Preclusion List” for Part D Prescription Drug Program and Medicare Advantage

Rather than requiring Medicare enrollment (or valid opt-out), CMS proposes a risk-based approach that would enable the agency to focus on prescribers and providers who pose threats to the Medicare program and its beneficiaries, while minimizing the burden on those who do not. Toward that end, CMS proposes to establish a “preclusion list” of “demonstrably problematic” prescribers and providers with the goal of preventing payment for Part D drugs prescribed or services rendered to MA enrollees by those on the list.

While the Alliance appreciates CMS’ efforts to reduce administrative burden on physicians, we have some concerns with the preclusion list proposal. As described, CMS would compile a “preclusion list” of prescribers and providers who:

- Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.
- Have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

CMS will consider “*the seriousness of the conduct underlying the prescriber’s revocation*”; “*the degree to which the [prescribers/providers] conduct could affect the integrity of the [Part D/MA] program*”; and, “*any other evidence that CMS deems relevant to its determination,*” when including certain prescribers/providers on the preclusion list.

We are deeply troubled by these subjective criteria in light of the serious professional consequences inclusion on CMS’ preclusion list may have on prescribers/providers. While CMS affords prescribers/providers an appeals process, rigorous, objective standards are warranted for purposes of adding prescribers/providers to the preclusion list. And, those criteria must be subject to notice-and-comment rulemaking. ***We urge CMS to modify its preclusion list criteria in the final rule consistent with our comments.***

Reducing Provider Burden Associated with Medicare Advantage Medical Record Requests

As part of its ongoing efforts to reduce regulatory burden, CMS seeks stakeholder feedback on the nature and extent of medical record documentation requests by MA plans, including ideas to address the burden.

Specialty physicians face a tremendous burden associated with medical record requests from MA plans generally seeking to improve their risk score and increase their Medicare payments. While some medical record requests are associated with CMS-initiated MA Risk Adjustment Data Validation (RADV) audits, many others are not. Specialty practices face extreme difficulty discerning the difference, as MA plans are not forthcoming with the nature of their requests. Contractors hired to assist with these audit efforts are generally unable to answer this basic question.

Moreover, the volume of medical record requests is tremendous, and coupled with untenable submission deadlines – sometimes as little as a few days. The medical record demand letters are not clear as to whether extensions will be granted when practices are unable to submit the documentation by the stated deadline.

Finally, multiple MA plans are contacting practices to make entirely separate demands for their unique review processes. Requirements for complying are complicated and confusing for already burdened practices.

We urge CMS to require MA plans to:

- ***Follow a standardized process for all medical record requests;***
- ***Clearly identify the nature of their medical record request (e.g., RADV, other purpose) and provide written documentation when requests are mandated as part of CMS-initiated audits;***
- ***Provide reasonable deadlines for medical record submissions, as well as a process for extending the submission deadline for extenuating circumstances;***
- ***Limit the number and volume of medical record requests (e.g., no more than once per year and no more than 20 records per physician); and***
- ***Allow practices to submit medical records through a secure web-portal, on CD/DVD, or by fax, when possible.***
- ***Reimburse practices for completing medical record requests at a rate no less than is set under State law.***

We appreciate the opportunity to share our feedback on these important issues facing specialty physicians and the beneficiaries they serve. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons