Sound Policy. Quality Care.

April 25, 2022

Jonathan Blum, MPP
Deputy Principal Administrator & Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

**RE: Recommendations to Improve Utilization Management and Advance Specialty-Focused Alternative Payment Models**

Dear Mr. Blum:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians and is deeply committed to improving access to specialty medical care through the advancement of sound health policy. Following our March 24 meeting, we prepared responses to key questions raised during the discussion, which are included herein. We hope to engage in an ongoing dialogue with you on these important topics.

## Prior Authorizations

As the Alliance discussed its concerns about utilization management, with a focus on prior authorizations, you asked whether there was value in prior authorization if it reduced post-payment medical reviews. In concept, Alliance organizations agree that pre-approval could be useful as a means to ensure payment for services rendered. However, our members' experience is that post-payment audits, and even recoupments, continue despite receiving prior approval. For example, some practices have told us that they received prior authorization for a service, but upon submitting a claim for payment, learn one of the following:

- the patients' coverage has lapsed or been cancelled,
- the patients' benefit plan does not include coverage for the approved service, or
- the service is no longer deemed "medically necessary."

In other words, there does not seem to be a link between prior authorization and reduction of post-payment review. And, frankly, we are not confident that it ever would. However, if prior authorization could guarantee payment and if the process for obtaining prior approval was streamlined and simplified, it would vastly improve these programs.

In addition, you asked about the prior authorization framework used in the Medicare fee-for-service program (for procedures) compared to the private sector (for procedures and medications), including Medicare Advantage (MA). Generally, Alliance organizations have heard from members that prior authorization processes – whether for procedures or medications – are plagued by inefficiencies that delay access to medically necessary services regardless of the payor. Alliance members who have been impacted by the prior authorization program for certain outpatient services are appreciative that CMS removed some services from the list, but continue to face challenges with those that remain.

To address prior authorization challenges in MA plans, Congress introduced bipartisan legislation – the *Improving Seniors Timely Access to Care Act* (H.R. 3173/S. 3018) – that would:

- Establish an electronic prior authorization process that would streamline approvals and denials;
- Establish national standards for clinical documents that would reduce administrative burdens for health care providers and Medicare Advantage plans;
- Create a process for real-time decisions for certain items and services that are routinely approved;
- Increase transparency that would improve communication channels and utilization between Medicare Advantage plans, health care providers, and patients;
- Ensure appropriate care by encouraging Medicare Advantage plans to adopt policies that adhere to evidence-based guidelines; and
- Require beneficiary protections that would ensure the electronic prior authorization serves seniors first.

Lawmakers in the state of Texas enacted, and have begun implementation of a "gold card" program that allows certain providers to bypass prior authorization protocols. Similarly, congressional leaders at the federal level are considering legislation that would exempt qualifying providers of certain items and services from prior authorization requirements under MA when the item or service was authorized at least 80% of time the previous plan year. CMS should consider implementing a similar program, or establishing a pilot program to test this concept, in its various programs.

Members of the Alliance strongly support the American Medical Association (AMA) Prior Authorization and Utilization Management Reform Principles, which describe 21 principles across five domains that are essential to any prior authorization program, and the Consensus Statement on Improving the Prior Authorization Process, which was penned by leading payers, and trade and professional organizations.

Concerning your question about a prior authorization dashboard, minimum statistics that should be included — which are also outlined in the AMA principles — are as follows:

- Health care provider type/specialty;
- Medication, diagnostic test, or procedure;
- Indication;
- Total annual prior authorization requests, approvals and denials;
- Reasons for denial; and
- Denials overturned upon appeal.

We also urge you to review the comments we shared with the Office of the National Coordinator for Health Information Technology, which discuss improvements in the prior authorization process that could be facilitated by electronic means.

Our organizations would be happy to discuss these recommendations in more detail and share additional experiences specialty physicians have faced during our upcoming meeting on April 28th.

## Step Therapy

Given time constraints, we did not have a chance to discuss our concerns about a related utilization management issue: step therapy. This is another particularly problematic area for Alliance organizations whose members rely on medication therapies, including targeted treatments to manage specialty conditions, such as rheumatoid arthritis, ulcerative colitis, inflammatory bowel disease and age-related macular degeneration. Our organizations have been working with federal lawmakers on the *Safe Step Act* (H.R. 2163/S. 464), which:

- Requires insurers to implement a clear, transparent process for a patient or physician to request an exception to a step therapy protocol.
- Codifies five exceptions to fail first protocols, requiring that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
  - A patient has already tried and failed on the required drug.
  - Delayed treatment will cause irreversible consequences: the drug is reasonably expected to be ineffective, and a delay of effective treatment would lead to severe or irreversible consequences.
  - Required drug will cause harm to the patient: the treatment is contraindicated or has caused/is likely to cause an adverse reaction.
  - Required drug will prevent a patient from working or fulfilling activities of daily living.
  - Patient is stable on their current medication, and their previous or current insurance plan has covered that drug.
- Requires a group health plan to respond to an exemption request within 72 hours in all circumstances and 24 hours if the patient's life is at risk.

Although the *Safe Step Act* would apply to ERISA plans, we believe the bill's provisions should be used for CMS' step therapy policies, which continue to be a significant challenge.

## Alternative Payment Models (APMs)

Even before the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 was signed into law and CMS established the Quality Payment Program (QPP), Alliance member organizations were developing quality measures, establishing clinical data registries, and working with payers on alternative payment and delivery models to improve efficiencies and patient care and to "raise the bar" within our respective specialty and subspecialty areas. Our feedback and that of other stakeholders led to many of the provisions included in the 2015 law, particularly those relating to the development of APMs and review by the Physician-Focused Payment Model Technical Advisory Committee.

During our meeting, we expressed concern about the lack of APMs for specialists, including the ability to engage in existing APMs, such as Accountable Care Organizations (ACOs). As we noted earlier, many of our specialty society members have invested significant time and resources on unrealized APMs. For example, surgeon members of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) set aside time— time that could have otherwise and more meaningfully been spent with patients— to assist CMS with the development of a potential model for longitudinal spine care, as well as stroke care. Both projects went nowhere, and it seemed like a colossal waste of nearly two years of their time and energy. Similarly, in 2018 the Department of Health and Human

Services (HHS) refused to implement for limited-scale testing Project Sonar, a community practice-based intensive medical home for patients with inflammatory bowel disease (IBD) based on AGA care pathways. In fact, HHS refused to implement any of PTAC's 10 recommendations for Medicare payment models saying, instead, that HHS would come up with its own models internally. In rejecting Project Sonar, HHS essentially negated years of work that went into developing an APM for gastroenterologists by Project Sonar and the American Gastroenterological Association.

In response to these concerns, you described some of the issues facing the agency in implementing small, specialty models (e.g., they may not yield requisite savings to ensure a reasonable return for the Medicare program). As a potential solution, you asked about specialty-focused APMs that were best suited as "standalone" models vs. those that could be plugged into a population-based or primary care model, such as an ACO. We appreciate this fundamental question and want to provide helpful feedback so the risk-bearing track of the QPP is no longer out-of-reach for the vast majority of our specialties. However, we would be remiss if we didn't express our frustration that the goals of MACRA have not been realized for specialists. In fact, had it been clear that specialists would have little ability to engage in the APM track, we would have urged alternative pathways. More importantly, pushing specialists into "primary care" or population-based models risks misrepresents their specific role in the diagnosis, treatment and management of health conditions and mischaracterizes their impact on quality and overall value. Worse, it suggests that primary care providers are best suited to serve as gatekeepers and determine whether specialty interventions are medically appropriate and necessary, which can negatively impact access to appropriate specialty and subspecialty care.

While the Alliance would prefer that CMS test standalone specialty models, we also would be willing to simultaneously work with CMS to explore the feasibility of developing episode-based measures and "shadow bundles" that could be embedded into ACOs or other population-based models of care. We also urge CMS to ensure better alignment between the specialty measures used in MIPS and APMs to minimize duplicative and unnecessary reporting burden and ensure that specialists have a mechanism to contribute to the APM's success within domains of care over which they have expertise and control. The Alliance would be happy to assist CMS with this effort, as well.

In addition, and to ensure specialists can participate in APMs, including those that are primary care or population-based, such as the Medicare Shared Savings Program and other ACO models, we urge CMS to adopt the recommendations we initially made in 2018:

- First and foremost, is critical that CMS test more models that are directly relevant and actionable for specialists. Models that specialists have direct control over— rather than some bigger, elusive entity— must be offered in addition to primary care or population-focused models.
- On an annual basis, publicly report data on the participation rates of specialists in ACOs and other population-based APMs by specialty/subspecialty.
- Establish requirements that prohibit ACOs from restricting specialist participation (e.g., "narrow ACO networks") or limiting specialists' ability to receive a portion of the ACO's shared savings.
- Provide ACOs with technical assistance that would allow them to analyze clinical and administrative data, improving their understanding of the role specialists could play in addressing complex health conditions, such as preventing acute exacerbations of comorbid conditions associated with chronic disease.

- Closely examine the referral patterns of ACOs to include collecting feedback from beneficiaries on access to specialty care and establish benchmarks that will foster an appropriate level of access to and care coordination with specialists.
- Develop measures for APMs, including ACOs, that would capture the percentage of physicians reporting to specialty-focused clinical data registries.
- Adopt specialty designations for non-physician practitioners to improve the ACO assignment methodology and ensure appropriate attribution of care, as well as more objective quality and cost evaluations and comparisons across provider types.

With regard to stand-alone models of care, as we mentioned earlier, our members have developed stand-alone models that they believed were appropriate, such as Project Sonar, to no avail. In order to best respond to your request, we urge CMS to share what threshold(s) a specialty model needs to meet to seek and anticipate implementation by the agency. It would also be helpful for the agency to share details on specialty areas the agency is most interested in and serious about developing a model, or which disease areas and service lines represent the biggest pain points from a quality and cost perspective.

Finally, we remind CMS that the Merit-Based Incentive Payment System (MIPS) track of the QPP is becoming increasingly irrelevant for many specialists due, in large part, to policies that disincentivize investments in the development and use of more specialty-specific quality measures. Unfortunately, CMS' MIPS Value Pathway (MVP) framework does little to address what is fundamentally broken with the program since it continues to rely on the current inventory of measures and scoring rules and fails to truly break down the silos between the four performance categories. While some of our members have had favorable experiences in MIPS, most are either frustrated or disengaged, making the need for specialty-relevant APMs even more critical.

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Thank you again for your thoughtful engagement and willingness to consider our feedback as we work toward our shared goal of serving patients covered by Medicare. We look forward to our upcoming meeting on April 28th at 11:30 AM ET to discuss these issues in more detail. Should you have any questions in advance of that discussion, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Otolaryngology-Head and Neck Surgery
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 Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society