



Sound Policy. Quality Care.

July 20, 2020
Mary Greene, MD
Director
Office of Burden Reduction & Health Informatics
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Newly Established Office of Burden Reduction and Health Informatics

Dear Dr. Greene,

On behalf of more than 100,000 specialty physicians from 15 specialty and subspecialty societies, the undersigned members of the Alliance of Specialty Medicine (the “Alliance”) write to congratulate you on leading the new Office of Burden Reduction and Health Informatics, and to share key opportunities for CMS to reduce administrative burden on specialty physicians and put patients over paperwork. The Alliance is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. To facilitate your review of our comments, below is a list of key recommended actions:

- Take deliberate steps to meaningfully improve specialty participation in the Quality Payment Program (QPP), to include making key revisions to the Merit-Based Incentive Payment System (MIPS) and prioritizing the availability of specialty-focused Advanced Alternative Payment Models (A-APMs).
- Address key concerns to improve the infrastructure for and facilitate interoperability and access to patient data.
- Replace administrative barriers that hinder patient access to medically necessary care and treatment, such as prior authorizations and step-therapy, with utilization management tools that rely on clinical data and evidence.
- Ensure access to care by requiring plan adherence to robust network adequacy standards that consider specialty and subspecialty medicine clinicians.

Quality Payment Program (QPP)

Merit-Based Incentive Payment System (MIPS)

A key factor in the Alliance of Specialty Medicine supporting the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was the law's promise to, unlike existing programs of the time, create a single, coordinated approach to physician quality reporting and value-focused performance measurement. We are

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now in the fourth performance year of the Merit-Based Incentive Payment System (MIPS); however, as of 2020, MIPS continues to rely on a siloed structure, where each performance category has a unique set of complex reporting and scoring requirements and a distinct set of metrics that often have no tie to other performance categories. Making matters worse, CMS makes substantial changes to the program's already complicated web of rules each year, such as modifying benchmarks, tweaking reporting thresholds, and scaling back on measures relevant to specialty physicians. Physicians find it extremely challenging to navigate this constantly changing landscape, even with specialty society and administrative staff support, and are increasingly forced to divert attention away from direct patient care to comply with requirements that are viewed by many specialists as only tenuously tied to improvements in quality and value of care.

Last year, CMS finalized plans to launch a new MIPS Value Pathways (MVPs) framework. The framework aims to create a more cohesive and meaningful participation experience for clinicians by moving toward an aligned set of measures that are more relevant to a clinician's scope of practice, while further reducing reporting burden and easing the transition to alternative payment models (APMs) through enhanced and timely performance feedback. While the Alliance strongly supports these goals, we are concerned that the MVP framework, as currently set forth, misses the mark in terms of addressing some of the most fundamental problems with MIPS. Listed below are our top recommendations for transforming MIPS into a more meaningful and effective program for both physicians and patients:

- ***Incentivize meaningful engagement among specialists by preserving choice, simplifying program requirements and scoring policies, and adopting policies that better incentivize the development and use of specialty-specific measures.***
 - Physicians should have the ability to participate in either an MVP or remain in the traditional MIPS pathway. The traditional MIPS pathway should also maintain multiple participation options that account for varying levels of resources among practices of different types and settings (e.g., lack of access to interoperable EHRs).
 - The MVP framework, or any future iteration of MIPS, should deconstruct the performance category silos so that physicians are not required to report data across four separate MIPS performance categories. Although the MVP framework attempts to bundle measures under a specific clinical topic, physicians still must comply with each of the four MIPS performance categories. Going forward, CMS should provide cross-category credit to alleviate reporting burden and to help physicians prepare for any future transition to APMs. For example, physicians that collect quality data through a Qualified Clinical Data Registry (QCDR) and use the registry's analytic feedback to track and improve performance should be eligible for automatic credit in the Quality, Improvement Activity, and potentially even the Promoting Interoperability category if the registry relies on the electronic exchange of data.
 - CMS should offer a more diverse selection of quality measures that more accurately capture the breadth of specialty care and are meaningful to patients of specialty physicians. We strongly believe that CMS' Meaningful Measures Initiative is misguided. Few physicians complain that they are overwhelmed by the wide selection of quality measures offered under MIPS—in fact, most physicians support a more diverse inventory of measures to ensure they are being measured on the care they actually provide and that performance results are actually relevant to their patients. Instead, physicians are overwhelmed by the program's complex reporting and scoring rules, and the goal posts that continue to shift from year to year. Simplifying these aspects of MIPS should be a

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priority for CMS as it aims to reduce physician burden and provide regulatory relief; not further reductions in the availability of specialty measures.

- At the same time, CMS also must adopt policies that better incentivize the development and use of new specialty-specific measures, including those created by QCDRs. Currently, physicians can only earn 3 points (out of 10) on a measure that does not have a benchmark. This results in a cycle where few physicians want to risk reporting on such measures, which further perpetuates the lack of a benchmark, which ultimately leads to the removal of the measure from the program before it even had a chance to make an impact. It is critical that CMS adopt policies that better incentivize the use of these measures, such as providing bonus points or cross-category credit, so that clinicians are motivated to use them.
- CMS also should recognize more innovative and cross-cutting ways of measuring clinicians under the Promoting Interoperability category, specifically. This category should look beyond certified EHR functionality and instead recognize the use of diverse technologies to harness and share clinical data for purposes of care improvement, such as the implementation of practice improvements based on clinical registry data that incorporates EHR data.
- Finally, quality and cost measurement should be standardized and streamlined across CMS programs and settings of care to avoid duplication. The Alliance is supportive of MIPS policies such as facility-based scoring, which recognizes that physicians in these settings are already being measured through their facility and therefore aims to reduce reporting burden and duplication of effort.
- **Work with relevant physician stakeholders on an ongoing basis to further streamline MIPS and to develop new and improved quality and cost measures.** These discussions should take place in a transparent and collaborative manner, but also in a timely manner that allows for expeditious adoption of more meaningful measures.
- **Implement the MVPs gradually through pilot testing that focuses initially on relatively simple conditions/procedures impacting relatively homogenous patient populations that also have existing measures and activities.** Our volunteer members are already spread thin assisting CMS with activities such as the development of episode-based cost measures, and they have little available bandwidth to devote to yet another comprehensive development project that starts from scratch. CMS should rely on existing measures and activities to the greatest extent possible. At the same time, if a specialty expresses interest in bringing its own innovative measures to the table (e.g., cost measures), the MVP framework should accommodate the consideration of such measures through a more streamlined and timely approval process.
- **Consider condition- or procedure-specific MVPs rather than specialty-specific MVPs.** Many specialties are divided into sub-specialties that have important distinctions in terms patient populations, procedures, and patterns of care. For example, within neurosurgery, there are surgeons that focus almost exclusively on cerebrovascular care (i.e., stroke) and surgeons that focus almost exclusively on spine care. It would be inappropriate to hold all of these surgeons to the same set of metrics. At the very least, we urge CMS to consider the use of separate or stratified benchmarks to accurately account for this diversity and ensure apples-to-apples comparisons of performance.
- **Avoid the use of administrative-based population health measures.** Although these measures are meant to reduce reporting burden since they are calculated automatically by CMS, they do not result in actionable feedback for specialists. They also do not typically provide a complete picture of a clinician's quality due to the limitations of billing data. Furthermore, they require a large sample to

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produce reliable results, which makes them potentially appropriate for facility-level or accountable care organization (ACO)-level programs, but presents challenges in a clinician-focused program such as MIPS.

- **Customize Promoting Interoperability requirements.** CMS should work with specialty societies to develop an inventory of Promoting Interoperability measures that look beyond EHR functionality and instead recognize diverse and innovative ways of sharing and otherwise making use of electronic health data to improve clinical outcomes (e.g., implementation of practice improvements based on clinical data registry data that incorporates EHR data).
- **Continue efforts to provide enhanced and timelier clinician feedback.** The Alliance appreciates CMS' interest in providing more meaningful and timely performance feedback to physicians. Ideally, data should be presented in real-time and in a manner that helps clinicians better understand their practice patterns in terms of both cost and quality so that they are better prepared to potentially transition to APMs. Data provided by CMS to date—particularly cost data-- has been untimely and difficult to interpret. CMS should continue to work with stakeholders to refine the format in which data are presented and to consider more efficient ways to merge claims data with existing clinical data collected from registries to ensure a more complete picture of care.

In general, in order for MIPS to produce data that will drive improvements and inform patient decision making about specialty care, CMS must preserve choice in terms of MIPS measure selection and participation options and adopt flexible policies that incentivize meaningful engagement by specialists rather than policies that marginalize them.

Alternative Payment Models

Under the current QPP, specialists are generally limited to participation in MIPS, given there is a scarcity of advanced alternative payment models (A-APMs) and the majority focus on the delivery of primary care services. In the case of the Medicare Shared Savings Program (MSSP), specialists may participate in accountable care organizations (ACOs), but ACOs – especially physician-led ACOs – tend to limit their involvement. While the Medicare Payment Advisory Commission's (MedPAC) analysis of the 2016 MSSP ACO public use file indicates that about 60 percent of ACO-participating physicians are specialists, it is not clear *which specialties* are predominately included. The Alliance and other stakeholders have repeatedly asked that data on specialty participation in alternative payment models (APMs) be made publicly available, particularly for ACOs, but to no avail.

As we approach the *fifth* performance year of the QPP, we are dismayed that meaningful pathways for specialists to engage in the A-APM track have not been established, and that specialists remain at a disadvantage. This disparity has persisted for far too long and must be addressed swiftly to ensure specialists have the same access to the A-APM track as primary care practitioners to realize the reduced reporting burden and increased financial incentives that were envisioned when MACRA was enacted.

To address our concerns, we make the following recommendations:

- Establish A-APMs for specialists, considering recommendations from the Physician-Focused Payment Model Technical Advisory Committee (PTAC), as well as models brought directly to the Innovation Center. It is critical that A-APMs targeting specialists are developed with direct input from clinical expert members of those specialties;

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- Provide ACOs with technical assistance that would allow them to appropriately 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 and establish benchmarks that will foster an appropriate level of access to and care coordination with specialists, in addition to collecting feedback from beneficiaries on access to specialty care;
- Examine how the calculation of qualifying APM participant (QPs) thresholds creates incentives or barriers to specialty engagement, and make adjustments necessary to ensure that APM entities are not penalized for engaging specialists;
- Require ACOs to maintain and publicly-post a list of specialty physician participants on their websites, including their specialty designation;
- Adopt specialty designations for non-physician practitioners to ensure specialty practices are not limited to participation in a single ACO; and
- Release data on specialty participation in APMs, including bundled payment programs.

Interoperability and Access to Data

The Alliance appreciates and supports both CMS' and ONC's recent efforts to promote game-changing innovations in electronic health information that are intended to minimize errors, improve care coordination, reduce physician burden, lower costs, and enhance consumer experience. However, we also have serious concerns that if data are unleashed too rapidly and without adequate standards, parameters, and context, it will be uninterpretable to patients and at considerable risk for misuse. If the goal is to make patients better healthcare consumers, then it is critical for both CMS and ONC to carry out these reforms carefully and gradually to ensure that data can be shared with patients in a meaningful and usable format. If the infrastructure is not first in place to ensure these protections and ensure that physicians are not faced with costly responsibilities to guarantee access to such data, this surge of data will simply overwhelm patients and the physicians who care for them and potentially be misapplied in ways that impact coverage, access to care, and the physician-patient relationship.

Utilization Management

Prior Authorization

Prior authorization may be the number one administrative burden that physicians, particularly specialists, and their patients face in accessing medically necessary healthcare services. In fact, a survey of 1,000 specialty physicians conducted by the Alliance found that:

- 87.13% have delayed or avoided prescribing a treatment due to the prior authorization process;
- 94% report that this increased administrative burden has influenced their ability to practice medicine;
- 82% state that prior authorization either always (37%) or often (45%) delays access to necessary care;
- Prior authorization causes patients to abandon treatment altogether, with 32% reporting that patients often abandon treatment and 50% reporting that patients sometimes abandon treatment;
- 63% report having staff who work exclusively on prior authorizations, with one-half estimating that staff spend 10-20 hours/week dedicated to fulfilling prior authorization requests and another 13% spending 21-40 hours/week; and

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- Ultimately, the majority of services are approved (71%), with one-third of physicians getting approved 90% or more of the time.
- Even when prior authorization requirements were met, one fifth of physicians reported *still* receiving a denial 20 or more times in the preceding year.

A bipartisan group of more than 100 Members of Congress recently raised concerns about prior authorization practices in Medicare Advantage (MA), urging CMS to provide direction to increase transparency, streamline PA, and minimize the impact on patients. Specifically, these Representatives – with support from the Alliance – urged CMS to:

- Issue guidance to MA plans to dissuade the widespread use of prior authorization and to provide direction to the health plans to increase transparency, streamline prior authorization, and minimize the impact on beneficiaries;
- Ensure that prior authorization practices do not create inappropriate barriers to care for Medicare enrollees; and
- Collect data on the scope of prior authorization practices (i.e., denial, delay, and approval rates).
- While CMS has taken some action, several key recommendations have yet to be proposed, finalized or implemented.

In prior comments to CMS on modernizing Part D and Medicare Advantage, we asked CMS to require plans to adopt a streamline and automate prior authorizations by delineating those that are straightforward (i.e., where limited information is needed to render a determination) from those that are complex (i.e., where more detailed information may be necessary). For those that are straightforward, plans should use automated processes to render “instant” approvals. For those that are complex, plans should render a determination in less than 24 hours.

Step Therapy

We remain deeply concerned with CMS’ step-therapy policies, which require beneficiaries to try and fail “preferred” medications before accessing the physician-prescribed medication. These policies are particularly troubling as plans – by way of their pharmacy benefit managers (PBMs) – deem medications “preferred” based on the value of the financial incentive (i.e., the manufacturer’s rebate) to the PBM rather than clinical data or evidence, quality metrics, or anticipated patient outcomes. Beneficiaries who are denied coverage of medications recommended by their physicians can end up with poor health outcomes due to adverse health events, which can lead to costly hospitalizations and permanent disability. This is particularly true for beneficiaries with chronic diseases such as inflammatory bowel disease, rheumatoid arthritis, cancer, psoriasis, or age-related macular degeneration, who may respond differently to various medications used to treat these diseases.

The aforementioned 2016 survey of 1,000 specialists found that:

- 86% had experienced an occasion during which a stable patient was asked to switch from his or her medication by the insurer even though there was no medical reason to do so.
- 70% reported that, in the preceding year, they knew of *at least* ten times when their patients were unable to follow recommended treatment plans due to out-of-pocket costs.
- 93% reported needing to change a prescription to a different medication due to delay tactics from insurers related to the original prescription.

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In the era of personalized medicine, CMS' policies take a step backwards for those who rely on Medicare. We oppose step therapy in Medicare and urge the agency to prohibit the use of these policies in Medicare Advantage and Part D. With respect to all utilization management tools employed by plans, CMS should implement policies that prioritize the use of clinical data and evidence.

Network Adequacy

For several years now, the Alliance has expressed concerns about narrow provider networks in MA and health insurance exchanges. Narrow provider networks employed by these private plans impede access to medically necessary care and treatment, particularly when that care is provided by a specialty or subspecialty physicians. In addition to access challenges, narrow networks contribute to "surprise medical bills"¹ – a problem federal legislators are currently working to address.

We have urged CMS to revise its MA network adequacy criteria and return to quantitative network adequacy standards for exchange plans. We reiterate those recommendations here in the spirit of aligning such requirements and ensuring appropriate access to care.

- Return to quantitative network adequacy standards for exchange plans and revise MA network adequacy requirements, including specific standards for specialties and subspecialties;
- Require exchange and MA plans to maintain accurate, real-time provider directories;
- Require plans to provide reasonable notice regarding termination of a provider's in-network status, detailed information on the cause for termination, and options for re-entering the network.
- Establish specialty designation taxonomy codes for all specialties and subspecialties so they must be accounted for in exchange and MA plan network adequacy requirements; and
- Develop Quality Rating System (QRS) measures that tie network adequacy ratings to health plan quality scores and, for Medicare Advantage, capitation rates.

We appreciate the opportunity to share our recommendations for action and look forward to a productive dialogue with you and the Office of Burden Reduction and Health Informatics to ensure patients are truly prioritized over paperwork and have adequate access to specialty medical care. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

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¹ Surprise medical bills are prohibited in Medicare Advantage, but not in other private plans, including those in the health insurance exchange.

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