August 12, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244

Re: Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork

Dear Administrator Verma:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments in response to the Request for Information (RFI); Reducing Administrative Burden to Put Patients Over Paperwork, published on June 11, 2019.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to also educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to advancing policies that protect the ability of patients to receive high-quality care. We are supportive of the Centers for Medicare and Medicaid’s (CMS's) efforts to eliminate burdensome and unnecessary regulations and subregulatory guidance that take quality time away from the physician-patient relationship and can lead to physician burnout. We agree with the Agency that physicians should “spend less time on paperwork and more time on their primary mission—improving their patients’ health.”
Overview

CMS launched the Patients Over Paperwork Initiative (POPI) in 2017 and has garnered over 3,000 public comments from the clinician and stakeholder community, covering 1,416 distinct topics. Topics within the first round of public comment included but were not limited to: Audits and Claims; Documentation Requirements; Health Information Technology; Interoperability; Provider Participation Requirements; Quality Measures and Reporting; Payment Policy and Coverage Determinations; the Physician Self-Referral Law; and Telehealth. In this new RFI, CMS is soliciting input for new ideas not conveyed during their first RFI, as well as ideas that may help “broaden perspectives about potential solutions.”

In this letter, PAI provides input and recommendations on specific areas where CMS could focus its efforts in support of the POPI. We urge the Agency to take the following into consideration as it proceeds with implementation of any policies:

• Documentation requirements should be streamlined, and documentation information collected in electronic health records (EHRs) should be leveraged for other purposes, and that this is done in a way that is consistent with industry standards.
• Policies under the Quality Payment Program (QPP) need to be modified to better take into consideration the needs and resources of rural physicians.
• Greater alignment of Medicare and Medicaid payment and coverage requirements is necessary to reduce burden and unintended consequences.
• Need to modify the Recovery Audit Contractor (RAC) policies for more fair and transparent audits.

More detailed comments and recommendations on each of these follows.

Improving Accessibility and Presentation of Requirements for Quality Reporting, Coverage, Documentation, and Prior Authorization

As discussed above, documentation requirements can take away from face-to-face patient time and impact the care and services patients receive. PAI believes that documentation requirements should be streamlined, and documentation information collected in electronic health records (EHRs) should be leveraged for other purposes. Furthermore, CMS should align its efforts and ensure that they are consistent with industry standards.

Prior Authorization Processes

There is much variability across the board regarding workflow processes and data input (e.g., state, federal, vendor, setting) on how personal health information (PHI) is collected and shared. PAI believes it is important standardize data and processes surrounding prior authorization and ordering of services. This is especially critical as patients may receive care across different settings, as well as in different states, and standardization would help ensure that they continue to receive coordinated
and informed care. We believe it would be valuable to streamline and automate the processes for prior authorization of services which can delay critical patient care. CMS should consider how health plan information could be adopted into, e.g., EHRs for prior authorization. With the appropriate EHR infrastructure and data elements in place, physicians can ensure that patients receive necessary care faster without having to first go through a time-consuming prior authorization process.

Relatedly, EHR files and data pulls should be the first step and resource for audit and review purposes. Currently, during the prior authorization and audit processes, the entity requesting the information requires physicians and practices to download and print the files for review purposes. However, given the capabilities of EHRs, PAI believes that there should be a shift from reviews of paper records to electronic reviews, which could be then also be conducted remotely.

CMS should also issue new guidance and perform enhanced scrutiny of plan practices to ensure that physicians and patients do not face unnecessary and burdensome measures for lawfully covered services. CMS should also eliminate the use of pre-service organizational determinations (PSODs) and instead allow the use of advance beneficiary notices in the MA program in order to eliminate treatment delays.

**Health Information Exchanges (HIEs)**

PAI urges CMS to support existing and development of new HIEs that would reduce burden, improve information sharing, and interoperability for patients and physicians. However, we believe this funding should be extended and be provided for promoting interoperability across payers and health systems and hospitals as well. Furthermore, funding should be allocated to help support existing efforts rather than “recreating the wheel.” For example, in states where a “private” HIE or interoperability option and infrastructure is already in place (e.g., by a state medical society), focus should be on building upon and further expanding that existing infrastructure for interoperability purposes rather than trying to create something new from scratch. Similar to other recommendations in this comment letter, PAI once again urges streamlining the federal/national and state requirements for HIEs, as there are currently two different sets.

**Network Adequacy**

PAI urges the Agency to focus on network adequacy issues to ensure patient access to high-quality physicians and necessary services. Network adequacy standards should be refined to account for factors such as physicians’ experiences, specialty as well as subspecialty, capacity to accept new patients, seeing patients in a timely and regular manner for treatment, wait times, etc. This would better reflect whether the network includes all of the physicians and other health care providers needed to provide timely, comprehensive services to patients.

PAI also encourages the Agency to account for the impact of the time spent providing patient care by part-time and faculty physicians when determining whether network adequacy standards are being met. While a network may have 1,500 physicians, 1,000 could be spending most of their time in a faculty role or may be practicing part-time, which should be accounted for. For example, if each only have 1/26 FTE patient care time which is only 40 FTEs for those 1,000 physicians in addition to 500
FTEs for the remainder, totaling 540 FTEs for the network rather than 1,500 as initially suggested by the “number of practicing physicians in network.”

**Addressing Specific Policies or Requirements that are Overly Burdensome, Unachievable, or Cause Unintended Consequences in Rural Settings**

The policies and requirements under the Quality Payment Program (QPP) are burdensome and unachievable for physicians in rural settings. This is true for policies under the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) pathways, and they need to be modified to better take into consideration the needs and resources of rural physicians. For example, the current Advanced APM options are too high-risk for small and rural practices. PAI believes that lower risk standards should be adopted for Advanced APMs to entice small and rural practices to participate in value-based arrangements. Under the MIPS pathway, CMS has noted its intention to eliminate the claims-based reporting mechanism in future reporting years. PAI believes that claims-based reporting should continue to be an option for small and rural practices that may not have access to or the resources available to purchase EHRs.

**Simplifying Regulations or Operations that Pose Challenges for Dual-Eligibles and Those Who Care for Dual-Eligibles**

Modernization efforts need to ensure that the guiding laws and regulations at both the federal and state levels (i.e., Medicare and Medicaid levels) are updated and keep pace with health care delivery system innovations and advancements. These efforts need to be coordinated so that Medicare and Medicaid coverage and payment requirements are aligned, so that they are not conflicting and/or confusing or unfairly penalize physicians. For example, it is currently possible that a physician may adhere to the Medicare standard for dual-eligibles could be penalized for “violating” or not being in compliance with the state Medicaid standards. It is therefore important that the two sets of requirements “sync” to decrease confusion and avoid unintended consequences for physicians providing care to this high-needs patient population.

**Simplifying Beneficiary Eligibility and Enrollment Across Programs**

*Medicare Annual Wellness Visits*

Welcome to Medicare and Medicare Annual Wellness Visits play a key part in the Medicare program. However, to ensure program integrity and ensure that patients enrolling in Medicare are receiving appropriate care, CMS should clarify that primary care physicians are the only clinicians that can conduct and bill for Medicare annual wellness visits. Currently, MA plans and other payers may contract out these visits to third-party screeners. These third-party screeners do not have the clinical expertise that is required for these important visits. Furthermore, these screeners do not share the information they gather with primary care physicians or specialists prior to whom the patients are then referred to. Thus, this could result in an information gap for the physicians and/or duplication of services since physicians are not aware that these services have already been provided.
PAI believes that the Agency should prohibit MA plans from contracting with third-party screeners to conduct annual wellness visits. Should CMS continue to permit third-party contracting for these visits, the Agency should introduce more stringent requirements related to care coordination and patient continuity of care (e.g., timeliness of reports to the patient’s primary or specialty physician, electronic reporting of the information when there is a critical issue or problem with the patient, etc.).

Additionally, in some cases, MA plans may only cover some of the services that are covered by Medicare as part of these visits. For example, some MA plans may not cover a pap smear if a pelvic exam is conducted even though Medicare covers and provides payment for both services. It is important that for these visits MA plans be required to adhere to the Medicare payment policies for preventive services.

**CMS/CMMI Models and Demonstrations**

Many physicians participating in CMS and CMMI models and demonstrations have expressed concerns about the patient attribution and alignment methodologies. Physicians participating in these models may be responsible for the costs and quality of care of patients they are inappropriately attributed based on claims but who they saw sparingly. Physicians participating in these models should only be responsible for the costs and quality of care for patients they are truly responsible for. Relatedly, there are concerns and barriers with the volunteer alignment process which requires beneficiaries to log-in to MyMedicare.gov to make an election of their primary care and other physicians and providers. PAI believes alternative, less burdensome options for volunteer alignment under these models should be made available, e.g., in-office or telephone election.

**Further Modifying or Streamlining Reporting and/or Documentation Requirements or Processes to Monitor Compliance with CMS Rules and Regulations**

There are several modifications that can be made to existing rules and regulations to improve compliance and the audit processes. PAI believes that more fair and transparent medical audits are necessary to limit physician and practice exposure to significant administrative and regulatory burdens and expenses. These are necessary to minimize associated risks, including fatigue, burn-out, and financial failure.

**Streamlining Coverage and Payment Requirements**

As discussed above, the inconsistency between Medicare and Medicaid requirements can result in unintended but burdensome and negative consequences for physicians. PAI reiterates the need for aligning Medicare and Medicaid coverage and payment standards (especially for reimbursement and quality reporting purposes), and greater transparency and clarity on when the standards are distinct or deviate from one another. Furthermore, these efforts should align with other payers, as many physicians and practices report similar but slightly different information in different formats based on the payer/program. PAI believes that CMS should collaborate and other payers (e.g., Medicare Advantage plans) in these efforts.
Recovery Audit Contractors (RACs)

Currently, physicians are overwhelmed with the pre- and post-payment reviews and audits. PAI believes a more uniform, consistent, and standardized approach should be adopted for these processes. Additionally, standards need to be developed for auditors to ensure that only those who have the experience and appropriate credentials audit medical claims. The following criteria could be considered: clinical background, coding background/certification, experience with EHRs, etc.

The existing rules and regulations are complex and can be confusing. PAI believes greater focus needs to be placed on physician education about the requirements to decrease unnecessary audits and unreasonable penalties.

Furthermore, the contingency fee payment system for recovery audit contractors (RACs) incentivizes overzealous and inaccurate auditing practices, resulting in erroneous overpayment findings. For example, auditors could conduct a sufficient review with, e.g., 50 medical records/charts, but may demand 100+ due to how they are paid. PAI believes a retainer-based system or other system that is not based on the payment amount. A new payment system should create incentives for RAC accuracy and disincentives for inaccuracy.

Physicians should also be permitted to challenge the RACs’ decision to use extrapolation and a separate, timelier appeals track should be created for physician appeals. For example, while the extrapolation may use the correct formula, the RACs may be starting with the wrong sample size and could include and consider claims that are not relevant to the focus of the review. Alternatively, there could be consideration of creating a Medicare Magistrate Review program for RAC appeals involving lower dollar amounts.

Carrier Advisory Committee (CAC) Process

The CAC process has become less transparent and more difficult to navigate for physicians. The process should continue to serve as an important tool to enable physicians to be engaged in the development and refinement of local coverage determinations (LCDs), as well as to engage directly with the Medicare contractors. Unfortunately, physicians have become less engaged with the process as its complexity has increased with physicians sifting through topical areas rather than being able to directly determine what are covered and allowed charges by CPT and ICD 10 codes. PAI encourages the Agency to consider ways to simplify the CAC process to enable physicians to easily engage and seek the information they need.

Further Enabling Operational Flexibility, Feedback Mechanisms, and Data Sharing that would Enhance Patient Care, Support Clinician-Patient Relationships, and Facilitate Individual Preferences

Feedback Reports and Mechanisms

PAI believes sharing feedback reports and data on a timely and continuous basis is critical for physicians and practices as it equips them with better information about the patients they are caring for and the totality of care those patients are receiving. PAI believes that physicians need to have access to a holistic view into their patient’s health, allowing both parties to make more informed care
decisions. PAI encourages the Agency to share comprehensive feedback reports in a timely and as close to real-time as possible to improve the provision of care. This can be done through EHRs and HIEs (reiterating the need discussed above for supporting HIEs as a means for increasing operational flexibilities and patient-physician communication and relationship), as well as through the new Data at Point of Care initiative the Agency recently announced. Physicians should be provided the option to select the mechanism that is most convenient for them. We also believe in giving patients more visibility into their medical records and making their information more transparent to them so they can truly be partners in their care.

Direct Contracting
PAI believes that more patient-centered and -empowered options need to be offered under the Medicare program. Currently, if Medicare beneficiaries see physicians that opt-out of Medicare, they will generally have to pay for all services furnished by those physicians out-of-pocket. This often forces patients to terminate relationships with their physicians after they opt-out of the Medicare program. PAI believes that all patients should be able to enter into direct contracts with any physician—regardless of Medicare opt-in or opt-out status—for any item or service covered by Medicare. These patients could then submit claims for Medicare payments at an amount that would be charged if the physician participated in Medicare. This would give patients greater control over their health care decisions and costs.

Restrictions on Physician-Owned Hospital (POHs)
The restrictions placed on POHs has been a topic of debate for over a decade. Current restrictions on the formation and expansion of POHs were implemented in response to self-referral concerns and criticism, including that physicians would only refer healthy patients to a hospital in which they shared an ownership interest, and that physicians may overutilize the services in those hospitals given their self-interest. PAI understands the concerns that prevailed at the time. However, recent studies have countered these arguments, finding that these policy concerns are often “overstated,” and instead show that POHs perform equally well as non-POHs in quality and cost, and in some cases, provide even higher quality care at a lower cost.¹

Studies have found that, because POHs are not paid the same subsidies as other facilities, their quality rankings come at a lower cost to the Medicare program. Estimates suggest that under similar

regulatory structures, “POHs would generate about $10 billion in savings over a 10-year period.”

Furthermore, a study did not find any evidence that POHs “cherry-picked” their patients and did “not seem to systematically select more profitable or less disadvantaged patients or to provide lower value care.”

By imposing restrictions on POHs, current laws and regulations are restricting the development and expansion of these entities that have shown to increase quality and decrease costs at a competitive level with non-POHs. PAI requests that these restrictions be revisited and lifted to encourage more competition among physicians and between physicians and larger integrated health systems and hospitals, as well as increase patient choice for where and from whom they receive their care. Additionally, we believe this would contribute to addressing some of the vertical integration concerns discussed above.

State Certificate of Need (CON) Programs
State CON laws limit which entities can have imaging and certain surgical equipment. This restriction on who can provide certain services limits competition and resulting innovation in improvements in patient care. Furthermore, challenging CONs is often a costly process that creates a barrier for individual and small group practices who may have limited resources, even though winning exception to a challenged CON may be beneficial to improving patient care.

PAI understands the historical intent and rationale for the development of CON laws as a tool to address overutilization; however, the current health care environment has evolved, and it is necessary to revisit these to ensure that they are still appropriate given the needs of patients and system today.

Patient Translation Services
PAI believes there needs to be greater focus on the needs of different patient groups who may require translation services, including those who require language assistance or sign interpretation. Currently, lack of Medicare compensation for these services creates a disincentive for some clinicians to be able to offer services for these patients. Physicians are forced to bear the costs of providing special translation services without compensation. PAI believes physicians should be reimbursed for translation services and incentives should be adopted that further encourage these services.

2 Avalon Health Economics Study.
3 British Medical Journal Article.
New Recommendations Regarding When/How CMS Issues Regulations and Policies and How these can be Simplified

PAI commends the agency for focusing on interoperability requirements with the recent proposed rules and encourages the agency to continue pursuing those efforts and take into consideration PAI’s recommendations in response to those proposals. We also urge the Agency to continue efforts to simplify and reduce burden and complexity within the QPP. We continue to stress the need to simplify the QPP and make it more accessible for and applicable to physicians.

Conclusion

Overall, PAI supports CMS’ efforts to streamline and reduce unnecessary burdens placed on physicians. These adjustments must benefit all physicians and providers equally and should not be designed or structured simply for large health systems. These adjustments also should not disadvantage or be detrimental to small practices, but rather incentivize them to engage in programs and activities. Lastly, it is important that physicians and other clinicians not be penalized or held accountable for the actions of vendors, plans, and other third parties that are responsible for complying with the policies resulting from this RFI. We welcome the opportunity to work with the Agency to further implement and advance strategies and efforts to reduce burden in a meaningful and impactful way. If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI’s Executive Vice President and CEO, at k2strategiesllc@gmail.com.

Sincerely,

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute