



## COLLEGE of AMERICAN PATHOLOGISTS

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August 12, 2019

Seema Verma Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-6082-NC  
P.O. Box 8016  
Baltimore, MD 21244-1816

*Submitted electronically to: <http://www.regulations.gov>*

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

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the request for information on “reducing administrative burden to put patients over paperwork” (CMS-6082-NC). As the world’s largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

With this request for information (RFI), the Centers for Medicare & Medicaid Services (CMS) “solicits additional public comment on ideas for regulatory, subregulatory, policy, practice, and procedural changes that reduce unnecessary administrative burdens for clinicians, providers, patients and their families.” The CAP agrees that unnecessary administrative burden can interfere with providing important care and services to patients, and we share CMS’ desire to “increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple, and accessible.”

Toward these goals, the CAP in 2017 met with Department of Health and Human Services (HHS) officials to discuss regulatory relief and submitted formal comments offering suggestions for specific actions to incorporate into the agency’s regulatory relief agenda. We appreciate CMS’ work with the “Meaningful Measures” initiative and our ongoing conversations with CMS to ensure pathologists are able to fully participate in the Quality Payment Program (QPP). However, we continue to see added complexity and confusion in the QPP, and as we expressed in 2018 comments on the agency’s burden reduction proposed rule, the CAP is disappointed that many of our regulatory relief issues have not yet been fully addressed, including those related to the misvalued code initiative, Clinical Laboratory Fee Schedule reform, and local Medicare coverage determinations. The CAP continues to believe that our recommendations provide opportunities to not only reduce unnecessary administrative burden on clinicians and providers, but also to simplify the health care system, improve patient access to medically necessary services, and increase transparency and physician input.

The CAP continues to stress our ongoing regulatory relief priorities, but in response to CMS’ request for “new ideas not conveyed during [the] first RFI,” we have expanded our comments to include issues related to prior authorization, physician burden in obtaining data, rural health care, evaluation and management services, and the improvement of rulings communications.

### **Prior Authorization**

As CMS recognizes in this proposed rule, addressing administrative burden must include improvements to prior authorization processes. The CAP agrees with the American Medical Association (AMA) and

College of American Pathologists  
1001 G Street, NW, Suite 425W  
Washington, DC 20001  
202-354-7100



other stakeholders that prior authorization is often overused, costly, inefficient, opaque and responsible for patient care delays. In general, the CAP is concerned that utilization programs, prior authorization protocols, and other volume control methods that dictate or limit health care provider decision-making may impinge on the practice of medicine and could improperly encumber and curtail medically necessary clinical laboratory and pathology services.

Specific to pathology is the issue of laboratory benefits management programs, which dictate or limit health care provider decision-making related to the use of clinical laboratory/pathology services. For well-established clinical laboratory/pathology testing, the CAP believes such programs pose an unnecessary and counterproductive procedural encumbrance upon the practice of medicine with the potential to improperly curb medically necessary testing in order to benefit the financial interest of the payer. Laboratory benefits management programs and other prior authorization protocols should be transparently based upon peer reviewed published evidence, subject to routine and timely updating based upon accepted standards of medical practice, amenable to immediate override based on the medical judgment of the physician, and should be prohibited from facilitating business conduct that would have an adverse claims impact on a pathology/laboratory provider acting on an order for services from a health care provider in accordance with law. In any context, clinical decisions undertaken by prior authorization programs or protocols should be administered by providers who are at least as qualified as the prescribing/ordering physician whose decision-making is otherwise subject to utilization review.

The CAP urges CMS to limit prior authorization requirements to tests and services where it is needed most (e.g. highly esoteric molecular/genomic testing), and to streamline prior authorization processes where possible, including in Medicare Advantage plans, which will help ensure unimpeded access to medically necessary services and care.

### **Physician Burden in Obtaining Hospital-Owned Data for Registry Reporting of MIPS Measures**

Pathologists participating in MIPS need to report performance on quality measures. As CMS eliminates claims-based measures, pathologists become disadvantaged in the program because it is difficult or impossible to access data from hospitals' EHRs and Laboratory Information Systems (LIS). Pathologists need access to hospital-owned data to support their ongoing participation in MIPS. As pathologists working in and supporting hospitals, we should have access to our patients' data in the hospital's EHR and LIS. However, in many cases, this does not occur or is made extremely difficult. For example, a large number of pathologists who use the CAP's clinical data registry, the Pathologists Quality Registry, to report quality measures do not receive any data from their hospitals.

Data from hospitals includes critical information such as laboratory tests and utilization, turnaround times, blood product utilization, cancer diagnostic workups, etc. Without such data elements, these measures cannot be fully calculated and scored. Although hospitals claim they cannot share the data for privacy and security purposes, CMS has indicated that there are no regulations that impede hospitals from doing so. In addition, each hospital sets its own legal requirements for accessing data, which becomes a significant resource issue for pathologists, registries, and the hospitals themselves (since multiple specialties presumably approach the hospitals for data). The lack of data availability from hospitals is a significant resource problem for the system as a whole (nobody wins), and a particular problem for pathologists.

Since this is a particularly serious issue for hospital-based clinicians, we encourage both the Office of the National Coordinator (ONC) and CMS to come up with potential solutions to help improve the flow of information between hospital EHRs, LISs, and registries. In pursuit of this, the CAP also supports hospitals, physicians, and laboratories being held harmless from any unintended data breaches that might result from improved and increased interoperability. As such, we support the ONC's Information



Blocking exception Promoting Security of EHI (§ 171.203) to the Information Blocking provision as proposed in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule. The CAP supports ONC's efforts to promote the security of Electronic Health Information (EHI), as long as hospitals do not inappropriately deny access to their data based on the false premise that such transfer of data somehow violates the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To resolve this seeming conflict, the CAP urges the CMS and ONC to develop a hold harmless provision available to both owners and users of these data (hospitals, physicians, laboratories, etc.) for purposes of MIPS reporting, which will remove this obstacle to improved and increased interoperability and reduce burden on hospital-based clinicians reporting for MIPS.

### **Coding and Documentation**

The CAP has several recommendations for ways to improve coding and documentation requirements for Medicare or Medicaid payment, including discontinuing "unlisted" coding practices, minimizing the impact of evaluation and management (E/M) revaluation, and limiting use of independent analytic contractors.

First, the CAP believes Medicare Administrative Contractors (MACs) should discontinue directing physicians/providers to report "unlisted" codes when a specific AMA's Current Procedural Terminology (CPT) code exists. Additionally, "unlisted" codes should not be required by the MACs, as established HCPCS/CPT codes should (per statute and regulation) be considered proper for coverage and payment. Federal contractors should not be allowed to require physicians/providers to use "non-HIPAA" codes to report their services

Second, the CMS has proposed to significantly increase the payment for the office/outpatient E/M visit codes for CY2021 and add a new add-on CPT code for prolonged services. This revaluation of E/M services will negatively affect the payments of all other non-E/M services and procedures through payment redistributions. Policy changes such as these should never inflict harmful redistributions of Medicare payments away from providers and the patients they care for. These adjustments to the Physician Fee Schedule will cause industry disruptive reductions to sorely needed specialty care revenue that seriously will jeopardize patient care. The CAP urges the agency to be mindful of well-intentioned policy changes, particularly those that focus on specialty-specific interests, as such proposals often result in inappropriate redistributions of Medicare outlays that significantly impact the broader physician community and patients they care for. Modifications in payment and policy should be fair and balanced, ensuring no specialty favoritism over others, and directing Medicare revenues toward maintaining a robust network of participating physicians.

The CAP urges the agency to minimize the impact of these "burden reducing" E/M revaluations on to the medical community by:

- Reversing proposed decision to implement budget neutrality reductions to the Physician Fee Schedule pool as the increased expenditures for E/M provisions represent new regulations;
- Minimizing unintended impacts by applying any budget neutrality adjustments equally across all services, not excluding any specialties, procedures, or service codes; and
- Providing a five-year phase-in of the final relative values so the medical community can adapt to these disruptive changes.

Additionally, as part of CMS' initiative to improve payment accuracy and address potentially misvalued codes under the Physician Fee Schedule, Section 3134 (a)(K)(III) of the Affordable Care Act granted the HHS Secretary authority to hire independent analytic contractors to conduct surveys and collect data to establish a process for CMS to unilaterally change the physician work and practice expense relative value



units (RVUs), without any constraints (fiscal or methodological). The CAP rejects the notion that costly independent contractors play a useful role in valuing physician services and has requested that the Secretary use the discretion included in law not to place reliance on independent contractors in reviewing or establishing Medicare RVUs. Use of this authority represents a potentially costly regulatory burden that undermines the well-established non-governmental AMA CPT and RUC processes.

The AMA RUC has a credible, transparent mechanism that utilizes the expertise of the entire house of medicine to examine all the details of the physician work and practice expenses to accurately achieve relative valuation of every physician service on the Medicare Physician Fee Schedule. The use of independent contractors compromises the long successful history of physician involvement in providing valuation and methodological recommendations to the CMS for the Medicare program. Engaging contractors to create empirical models to value physician services also intrinsically moves CMS away from a resource-based methodology. The CMS should instead continue to recognize the AMA RUC process as the best available tool for reviewing and revaluing potentially misvalued physician services.

### **CMS Processes for Issuing Regulations and Policies**

Physicians, specialty society staff, and other stakeholders await the release of proposed and final Federal Register posted rulings each year. The release of rulings related to the Physician Fee Schedule and Quality Payment Program, as well as inpatient and outpatient hospital rulings, are particularly important. For instance, the Medicare Physician Fee Schedule proposed ruling is anticipated on or before July 1<sup>st</sup>, and the final ruling is anticipated on or before November 1<sup>st</sup> each year. The release of these rulings is rarely on these anticipated dates. Improving communication and reliability in issuing regulations and policies would help alleviate the cost and burden of analyzing, communicating, and responding to such rulings. Specifically, the CAP requests that CMS provide regular updates in advance of ruling releases to help inform stakeholders about anticipated timing, and that CMS be more predictable and transparent in issuing regulation and policies, including for the Qualified Clinical Data Registry (QCDR) self-nomination cycle and other Merit-based Incentive Payment System (MIPS) policies as described below.

#### QCDR Self Nomination Cycle

The CAP supports CMS' goals around using measures in the MIPS program to improve quality of care. New QCDR measures require substantial work for practices to implement, especially with the increasing complexity of measures and the movement toward automated data integration for reporting. Specifically, practices need to learn the new measure and specifications, and the data elements must be mapped from their Laboratory Information Systems (LIS). Very little data in pathology reports is in discrete data fields; thus, mapping of measures relies on pathologist-specific keyword searches and pathologist-specific localization in the pathology report. This is a highly resource-intensive process that takes several months in order to ensure measures are being captured and calculated accurately. Finally, practices generally focus on mapping the current year measures once they have submitted those from the previous year—which is in February or March for most practices. Thus, if a practice chooses to report QCDR measures, then data generally begins accurately populating a dashboard midway through the year at the earliest.

The CAP recognizes and supports that CMS' goal is for ongoing monitoring and improvement on these measures throughout the whole performance year. However, the above-described cycle is the reality for practices, and so the full benefit of using these QCDR measures to drive ongoing improvement is diminished when measures are effectively on a one-year cycle.

The current one-year provisional approvals do not allow sufficient time for measure implementation, data collection for the next year's self-nomination, and improvement opportunities for practices. It is unrealistic for most QCDRs to have sufficient data on new, complex QCDR measures for the self-nomination period.



The CAP would like to work with CMS on ways to lengthen the cycle time for provisional measure approval to at least two years. This will give practices the necessary time to implement measures, collect accurate data, create scoring benchmarks, and use the measures for improvement as intended.

#### MIPS Regulations and Policies

CMS has used sub-regulatory guidance on a number of MIPS issues that the CAP believes should be finalized through the formal notice-and-comment rulemaking process. This not only causes confusion but increases unpredictability in a program where the rules change every year, thus not allowing adequate time for physicians and practices to prepare for compliance.

One example is the guidance for the Eligible Measure Applicability (EMA) clusters. The EMA process determines the number of measures a physician should have reported on when a physician reported on less than the required six quality measures in the quality category of MIPS. We encourage CMS to publish these clusters during the performance year instead of after the performance year has ended. Not knowing which measures are in which EMA clusters causes confusion among physicians and practices who are trying to collect and report data for various quality measures, especially for physicians in those specialties (such as pathology) that do not have six measures available to report. Having access to the EMA clusters during the performance year would provide these physicians and practices with much-needed clarity and guidance on whether they would be penalized if they report on a certain measure, but not on another that could be included in the same measure cluster. This becomes especially important because, while some EMA clusters may appear related in scope, due to diverse practice settings and case mixes, the clusters may negatively impact many physicians and practices that simply do not perform services/see patients/examine specimens related to all the clustered measures and therefore would be unable to report on one or more of the clustered measures. In other words, just because a physician or practice can report on one measure in a cluster, this does not indicate he/she can report on the others. In order to create predictability for physicians and practices reporting for MIPS, CMS should publish EMA clusters with the proposed rule for each performance year.

Another example is CMS' recent publication via a guidance document on a new policy for the Promoting Interoperability (PI) category of MIPS. CMS issued guidance suggesting that non-patient facing groups would not be automatically reweighted for the PI category (as was the case in 2017 and 2018 MIPS performance years) unless 100% of the individuals in the group qualified for reweighting individually. This has caused much confusion for physicians and practices as it was a major change that affected them but was not vetted through the notice-and-comment rulemaking process. In addition, the CMS QPP website continues to have language suggested that non-patient facing groups do indeed qualify for automatic reweighting of the PI category for 2017 and 2018 MIPS. This modified policy has thus caused major concerns, and we encourage CMS to retract this until it can propose this change through rulemaking.

As the above examples indicate, sub-regulatory guidance on important MIPS policies causes confusion and unnecessarily increases burden on physician and practices trying to comply with MIPS. As such, the CAP encourages CMS to be more transparent and to propose major policy changes via the formal notice-and-comment rulemaking process. This allows predictability, adequate vetting, and input from all stakeholders as well as enough time for physicians and practices to prepare for compliance with MIPS.

#### **Rural Health Care**

The CAP has concern with policies that make it increasingly difficult for laboratories to continue to offer sophisticated, state-of-the-art testing to enrollees, and for laboratories to continue to serve the rural and smaller hospitals that have relied on them. In particular, increasing regulatory burdens (including reporting requirements under the Quality Payment Program) and decreasing reimbursement (including inaccurate



payment rates under the revised Clinical Laboratory Fee Schedule) continue to put pressure on rural health care providers and result in decreased access to care for rural patients. In fact, many of the regulatory burdens discussed in these comments have a harsher impact in rural areas, as the cost of providing laboratory testing in these areas is higher with fewer resources and support than in urban areas. Additionally, physicians already face uphill negotiations with insurers due to antitrust inequities and health care industry consolidations, but this situation will likely get worse under many of the surprise billing proposals moving forward at the federal level.

Rural patients are especially impacted by the inadequacy of insurance networks. In the best interest of the patient, regulators should ensure health plans maintain robust networks of physicians to ensure timely access to care for all insured patients. Specifically, CMS' Market Stabilization Final Rule<sup>1</sup> significantly modified the agency's approach to network adequacy for Qualified Health Plans (QHPs) by "deferring to States with sufficient network adequacy review (or relying on accreditation or an access plan)" in an effort to "lessen the regulatory burden on issuers" and "recognize the primary role of States in regulating this area." In fact, CMS' QHP Application/Network Adequacy Template<sup>2</sup> does not include pathology as a medical specialty that plans can demonstrate having in their networks. Not surprisingly, these policies have diminished any incentive for health plans to enter into fair and reasonable contracts with many hospital-based specialists, including pathologists, to provide services at appropriate in-network rates. More importantly, these policies have exacerbated what has been deemed an epidemic of "surprise billing" because it does not address the underlying problem – requiring insurers to have an adequate network of physicians.

Not only is this a problem in the Marketplace, but also in Medicare Advantage (MA). CMS uses quantitative measurements of network adequacy for MA plans, which are collectively referred to as network adequacy criteria; however, many hospital-based specialties, such as pathologists, are not accounted for in these metrics<sup>3</sup>. In its 2019 Medicare Advantage Final Rule<sup>4</sup>, CMS noted its intent to consider new measures that would hold MA plans accountable for access to medical specialists; however, CMS has yet to propose such measures.

Through these policies, the agency has relinquished its responsibility for establishing and enforcing network adequacy standards at the federal level, leaving States and accrediting bodies to ensure patients have adequate access to physicians. Unfortunately, most states have failed to adopt laws, such as those included in the National Association of Insurance Commissioners' (NAIC) Health Benefit Plan Network Access and Adequacy Model Act – to ensure all insurers maintain adequate provider networks. And, accrediting bodies do not include measures that look at access to various specialists. More importantly, these entities do not have any enforcement capabilities, even if they measured broad physician access.

To address these challenges, we urge CMS to return to quantitative network adequacy standards<sup>5</sup> for QHPs and revise Medicare Advantage Organization network adequacy requirements, adding hospital-based specialties to the list for which such plans have a specific standard. In addition, we urge CMS to

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<sup>1</sup> <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-07712.pdf>

<sup>2</sup> <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/EcpNetworkAdequacyTemplate.xlsm>

<sup>3</sup> <https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/2018-Network-Adequacy-Guidance.pdf>

<sup>4</sup> <https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

<sup>5</sup> <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2017-Letter-to-Issuers-2-29-16.pdf>



develop “Star rating” measures that connect bonus payments and capitation rates to whether plans maintain adequate physician networks.

### **Medicare Coverage Processes**

Most Medicare coverage decisions are local, and the local coverage determination (LCD) process is a vital part of ensuring Medicare patients receive optimal care through appropriate access to services and technologies. However, the CAP continues to seek improvement in the LCD process through transparency and consistency in the use of medical and scientific evidence in coverage determinations. At times, we have seen how coverage decisions ignore medical evidence and Medicare program requirements. Most alarming is the extent to which Medicare administrative contractors are simply replicating LCDs, which are intrinsically local in their application and effect, from another jurisdiction without meaningful consideration or timely feedback from stakeholders.

On October 3, 2018, CMS announced the revision of Pub. 100-08, Chapter 13 of the Medicare Program Integrity Manual, which outlines the current LCD process and Medicare Administrative Contractors (MACs) requirements. The revisions reflect policy process changes in response to the 21st Century Cures Act and stakeholder comments, including from the CAP. In announcing these changes, CMS acknowledged concern about transparency, ineffective solicitation of stakeholder feedback, and concern that Contractor Advisory Committee (CAC) meetings are not open to the public.

While CMS adopted some of the CAP’s recommendations in the areas of open meetings and upfront disclosure of evidence, these changes do not address reconsideration and appeal shortcomings, or process compliance issues. Specifically, the CAP has advocated for a process for providers and suppliers to appeal a MAC’s reconsideration decision to CMS, rather than limiting reconsideration to the MAC that authored the LCD. The CAP also requested that reconsideration requirements should be broadened to include reasonable assertions that the MAC’s conclusion misinterpreted existing evidence, as is currently allowed with NCDs. It remains the case that, without new evidence, LCDs are functionally unreviewable once they become final, and that there is no independent review process.

Additionally, the CAP has argued that widespread adoption of replicated LCDs by MACs constitutes an evasion of the requirements of the more rigorous NCD process. No progress was made in this area in the manual revisions, and the CAP continues to seek a solution that would prohibit a MAC from replicating LCD determinations without following in both form and substance the specified process for LCD development in its jurisdiction(s).

Again, the CAP appreciates the recent steps taken by CMS to increase stakeholder engagement in the process and to outline CMS’ expectations for MACs. We will continue to engage with CMS on this issue.

### **Clinical Laboratory Fee Schedule**

Given the integral roles pathologists play in ensuring availability of clinical laboratory services, overseeing the quality and appropriateness of laboratory testing in their medical communities, and developing laboratory tests, the CAP and its members have a significant stake in the implementation of the Protecting Access to Medicare Act (PAMA). Like CMS, the CAP seeks to minimize disruption to the laboratory community and to ensure access to laboratory services for Medicare beneficiaries. However, the CAP and many other stakeholder groups have identified flaws in PAMA’s underlying data collection, including the need for more complete data collection to ensure accurate PAMA payment rates.



As we noted in our 2019 Physician Fee Schedule comment letter, CMS states that the data used to calculate the CY 2018 CLFS rates was “sufficient and resulted in accurate weighted medians of private payor rates.” Yet CMS’ definition of the term “applicable laboratory” continues to exclude almost all hospital laboratories. CMS’ failure to include in payment reporting such a large portion of the laboratory market results in a skewing of the PAMA payment rates to reflect disproportionately large commercial clinical laboratories. We remain significantly concerned about the impact this will have on availability of quality patient care through access to medically necessary laboratory testing. The CAP believes that more complete data collection is necessary to ensure the accuracy of the resulting rates.

We appreciate CMS’ willingness to evaluate policies that could lead to including a broader representation of the laboratory market for the next data reporting period, including the exclusion of Medicare Advantage plan payments from total Medicare revenues and the addition of the Form CMS-1450 14x Type of Bill to the applicable laboratories calculations. We urge CMS to continue making the PAMA methodology changes necessary to include all segments of the industry, thereby ensuring more accurate PAMA rates and continued access to laboratory tests for Medicare patients.

Finally, as CMS contemplates approaches to addressing payment of automated test panels (ATPs) under PAMA, the CAP continues to express frustration over the flawed Government Accountability Office (GAO) 2018 report, which suggested that initial PAMA reimbursement reductions should have been more severe. The GAO recommendations ignore statutory requirements and demonstrate a serious misunderstanding of actual, real-world billing practices of clinical laboratories. Especially as it relates to the use of bundled rates for panel tests, we urge CMS to provide updated information to the GAO in response to their recommendations, and to consider the importance of context and data before proposing any further action that could lead to adverse and unintended consequences.

### **Summary**

The CAP appreciates HHS’s efforts to improve the regulatory environment for physicians and we thank the agency for the opportunity to provide regulatory relief items of concern to pathologists. We believe the CAP’s aforementioned regulatory relief priorities, including addressing prior authorization, physician burden in obtaining data, rural health care, evaluation and management services, and the improvement of rulings communications, will assist CMS in its goal of reducing administrative burden while improving access to medically necessary services for patients, increasing transparency, and providing additional opportunities for physician input. Please direct questions on these comments to Elizabeth Fassbender (202) 354-7125 / [efassbe@cap.org](mailto:efassbe@cap.org) or Todd Klemp (202) 354-7125 / [tklemp@cap.org](mailto:tklemp@cap.org).