



11/19/18

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3346-P
P.O. Box 8010
Baltimore, MD 21244-1810

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

Re: Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Dear Administrator Verma:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule titled “Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction” (CMS-3346-P). 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 proposed rule, the Centers for Medicare & Medicaid Services (CMS) seeks to reform Medicare regulations “that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers.”¹ The CAP shares CMS’s desire to minimize regulatory burden and has previously met with Department of Health and Human Services (HHS) officials to offer suggestions for specific actions to incorporate into the agency’s broader regulatory relief agenda. We are disappointed many of these actions have not yet been taken, including addressing the misvalued code initiative, implementation of the Medicare Clinical Laboratory Fee Schedule (CLFS) reform, and issues related to alternative payment models. The CAP believes these and other areas provide opportunities to not only reduce administrative burden, but increase transparency and physician input while improving access to medically necessary services for patients.

We acknowledge that CMS has taken steps in some areas, such as local coverage determination process updates, but we continue to believe further action is required. Therefore, and in response to CMS’s request for public comment “on additional proposals or modifications... that would further reduce burden on Medicare and Medicaid participating providers and suppliers,” we continue to stress the CAP’s regulatory relief priorities, outlined below. Further, while the CAP understands the interest in simplifying and streamlining regulations, we explain here how the specific change related to autopsies would have a negative effect on quality assurance, medical education, and patient care.

Medical Staff: Autopsies (§ 482.22(d))

In this proposed rule, CMS suggests removing the regulation at § 482.22(d) that recommends a hospital’s medical staff attempt to “secure autopsies in all cases of unusual deaths and of medical-

¹ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-19599.pdf>



legal and educational interest.” Instead, CMS proposes to defer to state standards, laws, and regulations.

The CAP strongly opposes elimination of the current CMS autopsy standard.² The extant policy recommends that autopsies be sought and does not impose requirements on hospitals beyond having a policy governing how permissions would be acquired and results conveyed. Nothing about the current policy requires hospitals to perform any number of autopsies, and thus there is no real burden relieved by rescinding the policy. Rather, we believe removal of this policy would open the door to not performing or offering autopsies, which will have a significant downstream impact on public health, patient care, organ donors/donations, families, and potential health or genetic predispositions to diseases/disorders. In 2015, the National Academies of Science, Engineering, and Medicine specifically cites autopsy as a key tool for ensuring the delivery of quality health care and even recommends strategies for increasing autopsy numbers.³

Autopsy plays a unique and indispensable role in supporting the ability of health care professionals to improve and furnish high quality patient care. Conversely, failure to provide autopsies in appropriate circumstances would have an adverse effect on quality assurance and education, as well as on its valuable and meaningful role as a service to grieving families. Gratuitous elimination of this policy would further weaken the autopsy, a procedure that historically and currently contributes substantially to both education and patient care. If CMS does in fact believe that autopsy advances medical knowledge, as is stated in the proposed rule, supporting autopsy performance in principle should be the gold-standard of its recommendation in this area of patient care.

However, the current policy as stated conflates the very different roles and circumstances of hospital and medico-legal autopsies, the latter of which are mandated by law and are unrelated to whether an autopsy is requested by care providers or families. Therefore, the CAP would support clarification of the policy language regarding medico-legal autopsies. Further, we agree with CMS that hospitals need to know their state or local laws with respect to medico-legal cases and need to appropriately report deaths to their local medical examiner/coroner/medicolegal death investigation authority. Hospitals should not be trying to obtain family permission in such cases and ought not perform such autopsies without first consulting that authority.

The CAP’s Regulatory Relief Priorities

As expressed above, other areas where the CAP seeks regulatory relief include the following:

(1) Local Coverage Determination (LCD) Reform

The vast majority of Medicare coverage decisions are local, and the LCD process is a vital part of ensuring Medicare patients can lead better lives through improved access to services and technologies. However, the CAP seeks 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.

² (d)Standard: Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed. 42 CFR§482.22 (d).

³ National Academies of Sciences, Engineering, and Medicine. 2015. Improving diagnosis in health care. Washington, DC: The National Academies Press.



Most alarming is the extent to which Medicare administrative contractors are simply adopting LCDs from another jurisdiction without thoughtful discussion 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 those 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 go far enough, and additional steps must be taken to address both reconsideration and appeal shortcomings, as well as 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. CMS did not take steps in this area. Therefore, it remains the case that without new evidence, LCDs are essentially 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 form and in substance the specified process for LCD development in its jurisdiction(s).

Again, the CAP appreciates recent steps taken by CMS to increase stakeholder engagement in the process and outline CMS's expectations for MACs, and we will continue to engage with CMS on this issue. However, we would also urge CMS to support legislative efforts, such as the Local Coverage Determination Clarification Act, that would help ensure the needed improvements are enacted.

(2) Misvalued Code Initiative

Section 3134 (a)(K)(III) of the Affordable Care Act (ACA) 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 viable role in valuing physician services and has requested that the Secretary use the discretion included in law not to rely on independent contractors to review and establish Medicare physician relative values.

Instead, the American Medical Association/Specialty Society RVS Committee (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 value 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 moves CMS away from the resource-based methodology.



(3) Delivery System and Payment Reform Models: CMMI and PTAC

The CAP is supportive of innovative health care payment and delivery models, and we believe more opportunities are needed to participate under the Advanced APM track of Medicare's Quality Payment Program. However, the CAP is concerned that models are being submitted to the Physician Focused Payment Model Technical Advisory Committee (PTAC) and developed by the Center for Medicare and Medicaid Innovation (CMMI) that dramatically change providers' clinical decision-making without considering the input of those specialties impacted by the model. Thus, the CAP has continually sought to ensure physicians, especially the societies that represent physicians participating in and affected by new payment models, have input into new model development.

Specifically, in carrying out its statutory duties of testing innovative health care payment and delivery models that lower costs while "preserving or enhancing the quality of care," CMMI is required to consult clinical and analytical experts with expertise in medicine and health care management. Amongst those clinical experts and those with expertise in medicine and health care management, CMMI should be required to include associations representing physician specialties whose services are impacted directly in both primary and supporting roles by the Center's models. Consultation with specialty associations will help ensure that models developed in a manner that is transparent and focused on the best interests of the patient consistent with sound clinical input and practices.

Similarly, while the CAP is supportive of the PTAC's role in the review and recommendation of models developed by physicians, we believe that model submitters should be required to consult participating and affected specialties prior to model submission. PTAC provides an important opportunity for specialists to develop their own models and submit them for review and recommendation to the Secretary. However, at least three models recently submitted to the PTAC have included pathology services, yet the CAP was not consulted or even aware they encompassed pathology services until the models were posted for public comment. Model submitters should be required to evidence of consultation and concurrence from specialties participating in their models prior to their submission so that the PTAC can make recommendations on models that are truly physician-focused and enable meaningful contribution of their participants in enhancing the care of patients.

(4) The Medicare Access and CHIP Reauthorization Act: Quality Payment Program

As we have stressed in numerous comment letters, the CAP looks forward to continuing our engagement with CMS on elucidating the challenges of non-patient-facing providers to meaningfully participate in the Quality Payment Program (QPP), an inherently patient-facing program. Through the years, the CAP has advocated to increase flexibility for pathologists in a way that recognizes and accounts for the value pathologists contribute to patient care as non-patient-facing clinicians. As the QPP continues to be implemented, the CAP will continue to work closely with CMS to determine how to appropriately measure providers, including pathologists, who do not typically furnish services that involve face-to-face interaction with patients without simply adding unnecessary burden to meet regulatory requirements. The CAP continues to believe significant accommodations or alternate pathways are necessary.

(5) Protecting Access to Medicare Act (PAMA)

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 PAMA. Like CMS, the CAP seeks to minimize disruption to the laboratory community and ensure the ongoing provision of laboratory services to Medicare beneficiaries. However, the CAP and many other stakeholder groups have identified flaws in PAMA's underlying data collection, including the CMS interpretation of the PAMA statute in regard to the definition of applicable laboratories subject to data reporting.

As we noted in our most recent 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's definition of the term "applicable laboratory" continues to exclude the overwhelming majority of hospital laboratories. CMS's 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 a disproportionate weighting of 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 increase the accuracy of the resulting rates.

We appreciate CMS's willingness to evaluate policies that could lead to including a broader representation of the laboratory market for the next data reporting period, and we urge CMS to make 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.

(6) Cytology Proficiency Testing

The CAP has asked that CMS replace the current punitive and outdated cytology proficiency testing (PT) program with an alternative education program. In July 2017, the HHS Secretary's Office of Health Reform specifically requested a discussion with the CAP to focus on the current cytology PT requirements as well as the CAP's recommendations for reforms to the program. However, there has been no further action on this issue.

(7) Medicare Administrative Contractors (MACs) "Unlisted" Code Reporting Requirement is Burdensome for Physicians/Providers

As the CAP has previously expressed to CMS, MACs should discontinue directing physicians/providers to report "unlisted" codes when a more specific CPT code exists. Additionally, "unlisted" codes should not be required by the MACs, established HCPCS/CPT codes should (per statute and regulation) be considered sufficient for coverage and payment, and no "non-HIPAA" codes should be required by Federal contractors.

Summary

The CAP appreciates HHS's efforts to improve the regulatory environment for physicians and we thank you for the opportunity to provide regulatory relief items of concern to pathologists. In addition to opposing the change related to autopsies, we believe the above-listed CAP's regulatory relief priorities will aid CMS in its goal to reduce administrative burden, while also improving access to medically necessary services for patients, increasing transparency, and providing additional opportunities for physician input.

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The College of American Pathologists appreciates your consideration of these comments. Please direct questions on these comments to: Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.
