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October 8, 2019

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Administrator  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
CMS-1715-P, Room 445-G  
Hubert Humphrey Building  
200 Independence Ave, SW  
Washington, DC 20201

—Submitted electronically—

*Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care [CMS-3346-F]*

Dear Secretary Verma:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing in opposition to provisions of a recent Final Rule that eliminates the Medicare Conditions of Participation autopsy requirement (See [42 CFR § 482.22\(d\)](#)).

The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists (including medical examiners), other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

On September 30, CMS adopted a [Final Rule](#), eliminating or modifying existing Medicare regulations the Agency believes were unnecessary, obsolete, or excessively burdensome for health care providers and suppliers. Included among these new policies was the elimination of the Medicare Condition of Participation (CoP) mandate that hospital medical staffs should attempt to secure autopsies in *all* cases of unusual deaths and of medical-legal and educational interest (See 42 CFR § 482.22(d)). Instead, hospitals would be expected to defer to State law regarding such medical-legal requirements for autopsies. ASCP believes that state autopsy policies are insufficient to protect the public health. Because autopsies are critical to ensuring quality patient care, ASCP strongly opposes to this policy change.

In its [1999 June Report](#), the Medicare Payment Advisory Commission (MedPAC) stated the following about autopsies: "despite continuing advancement in diagnostic capability, errors in diagnosing patients are common and can result in adverse outcomes. **Research conducted since 1938 has consistently shown**

**that postmortem findings differ from pre-death clinical diagnoses between 35 percent and 47 percent of the time** (emphasis added)([Leape 1994](#), [Lundberg 1998](#)).” Another study found that **45 percent of autopsies revealed one or more undiagnosed causes of death, two-thirds of which were considered treatable** (emphasis added)([Nichols et al. 1998](#)). These studies validate the proposition that without the performance of an autopsy, it is not possible to say *with certainty* what caused a patient’s death. Autopsies remain the gold standard for identifying cause of death and are an indispensable quality assurance tool for evaluating and improving medical care.

Autopsies are also imperative to investigating and discovering unspecified disease as well as assessing the validity of new diagnostic or therapeutic modalities. In 2015, the National Academies of Sciences, Engineering, and Medicine (NASEM) conducted an investigation into medical errors and accurate diagnoses, and much of their work, findings and recommendations, relied on autopsy data. Their report, [“Improving Diagnosis in Health Care,”](#) outlined their findings on medical errors and the steps necessary to reduce the likelihood of diagnostic error. Without autopsy data, the ability to conduct research into medical errors and the quality of patient diagnoses could be significantly undermined.

Similarly, MedPAC [concluded](#) stating it **“believes that improved use of autopsies can aid in reducing errors as well as advance the field of medicine and enhance individual physicians’ knowledge (emphasis added).”** As a result, it has [recommended](#) that HHS should implement policies to increase the autopsy rate and urged that “Medicare policymakers should consider changing the hospital conditions of participation, revising payment mechanisms, or taking other steps *to promote autopsy use*. Similarly, NASEM has urged HHS to encourage the performance of more autopsies as part of their report, [“Improving Diagnosis in Health Care.”](#)

CMS’s new autopsy policy of deferring to *state laws governing the performance of an autopsy is woefully insufficient and does not adequate to protect patient health*. In preparing these comments, ASCP reviewed a Centers for Disease Control and Prevention (CDC) file, [Selected characteristic of deaths requiring autopsy](#), on state laws concerning autopsies. The CDC data provides clear and convincing justification of our concerns. Across all characteristics of death for which CDC presented data, few states have laws requiring autopsies or providing discretionary authority for their performance.

**As a replacement for CMS’s now rescinded policy that hospital medical staffs should attempt to secure autopsies in all cases of unusual deaths is a policy where only six states (required in IL and NJ, discretionary in PA, TN, WA, and WI) have a policy for cases of “suspicious/unusual/unnatural” death and only four states have adopted autopsy policies in cases of “unknown/unexplained” deaths.<sup>1</sup>** Moreover, for only one of the 31 characteristics on which CDC reported data was there a majority of states with an autopsy policy.

This clearly suggests that CMS believe that the CoP autopsy policy is redundant and that state laws are sufficient to replace this policy is flawed and without merit. Given the aforementioned data it is hard to see how the autopsy requirement was “redundant” or that there are many states with “more detailed, specific requirements.”

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<sup>1</sup> This particular characteristic provided the coroner or medical examiner with the discretion to perform an autopsy in cases believed to be in the “public interest.”

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NASEM cautioned that **“Without a dedicated focus on improving diagnosis, diagnostic errors will likely worsen as the delivery of health care and the diagnostic process continue to increase in complexity.”** It is hard to imagine how this focus will be maintained if autopsy rates erode further, as should be expected under the Agency’s new policy. The deference to State law rather than promotion of an overarching policy will introduce great variability in an era wherein most of medicine is striving for standardization of evidence-based best practices.

ASCP urges CMS to restore the Medicare CoP autopsy policy. Rather than eliminating the policy, CMS should embrace it, expand its reach, and implement a Medicare coverage policy to reimburse autopsy services under the PFS. Such a proposal could significantly advance medical care and help reduce the occurrence of medical errors and unnecessary deaths.

ASCP appreciates the opportunity to comment on this proposed rule. Please refer any questions to Matthew Schulze, Director, Center for Public Policy at 202-735-2285 or [Matthew.Schulze@ascp.org](mailto:Matthew.Schulze@ascp.org).

Sincerely,



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