

October 9, 2019

Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244

Re: Omnibus Burden Reduction (Conditions of Participation) Final Rule CMS-3346-F

Via e-mail: Seema.Verma@cms.hhs.gov

Dear Ms. Verma:

We, the undersigned organizations, are extremely disappointed with the Centers for Medicare and Medicaid Services (CMS) decision to remove the autopsy standards §482.22 (d) for hospitals finalized in the Omnibus Burden Reduction (Conditions of Participation) Final Rule. Contrary to the CMS's opinion, the removal of this standard will contribute to the further decline in the national autopsy rate and the quality of patient care will be impacted. The clinical autopsy is an important aspect of clinical service, providing clinicians with critical feedback regarding diagnostic accuracy, therapeutic efficacy, and medical complications.¹ To the patient's family, the clinical autopsy assists in providing closure by knowing or confirming the cause of death of the family member and the potential identification of heritable diseases which may have implications for those family members still alive. Moreover, the clinical autopsy has a unique and indispensable role in supporting the ability of health care professionals to improve and furnish high quality patient care by contributing knowledge in ways that can inform and/or change medical practice. For example, clinical autopsies performed on fetuses and infants, who developed intrauterine Zika virus infection, increased the understanding of how microorganisms can cause disease in a human host.^{2,3,4} Conversely, failure to provide autopsies in appropriate circumstances would have an adverse effect on quality assurance and education. It is clear, however, that autopsy rates have decreased substantially over the past decades in the United States. Data from the United States National Center for Health Statistics (NCHS) have shown that the overall autopsy rates (i.e., medicolegal plus hospital cases) decreased from 19.1% of all deaths in 1972 to 8.5% in 2007.⁵ These figures become even more striking when one separates the statistics for hospital and medicolegal autopsies. Although the medicolegal autopsy rate for the 35-year period rose

¹ M. Cristina Pacheco and Robyn C. Reed. Pathologist Effort in the Performance of Fetal, Perinatal, and Pediatric Autopsies: A Survey of Practice Archives of Pathology & Laboratory Medicine Feb 2017, Vol. 141, No. 2 (February 2017) pp. 209-214

² Shieh WJ, Guarner J, Layton M, et al. The role of pathology in an investigation of an outbreak of West Nile encephalitis in New York, 1999. *Emerg Infect Dis.* 2000;6(4):370-372.

³ Schwartz DA, Herman CJ. The importance of the autopsy in emerging and re-emerging infectious diseases. *Clin Infect Dis.* 1996;23(2):248-254

⁴ Schwartz DA, Bryan RT. Infectious disease pathology and emerging infections: are we prepared? *Arch Pathol Lab Med.* 1996;120(2):117-124

⁵ Blokker BM, Weustink AC, Hunink MG, Oosterhuis JW. Autopsy of adult patients deceased in an academic hospital: Considerations of doctors and next-of-kin in the consent process. *PLoS One.* 2016. 11(10):e0163811.

from 43.6% to 55.4%, the hospital clinical autopsy rate fell from 16.9% to 4.3%.⁶ The removal of this requirement, despite the encouraging commentary by the CMS for hospitals to retain their programs, will indeed further erode the national clinical autopsy rates.

Medicolegal autopsies are performed by forensic pathologists on behalf of medical examiner and coroner offices as mandated by local statutes, typically in cases of suspected homicide, suicide, accident, and unexplained deaths (unlike hospital autopsies). Based on the Centers for Disease Control and Prevention (CDC) file on state laws concerning autopsies, few states have laws requiring autopsies or providing discretionary authority for their performance for which the autopsy standard is applicable. Therefore, we believe the autopsy standard is **not** unnecessary, obsolete, or excessively burdensome on hospitals and other healthcare providers. Moreover, autopsies have a critical role in reducing inefficiencies and improving quality that moves the nation closer to a health care system that delivers value, high quality care, and better outcomes for patients at the lowest possible cost. For this reason, we respectfully ask the CMS to reinstate the Autopsy Standard as one of the Medicare Conditions of Participation.

Please contact Helena Duncan at hduncan@cap.org for any questions about this letter. We thank you in advance for your consideration of this request.

Sincerely,
College of American Pathologists
National Association of Medical Examiners
Association of Pathology Chairs
American Society for Clinical Pathology
American Society of Cytopathology

⁶ Harold Sanchez, MD, FCAP, (2019) Autopsy Request Process: Background, Consent for Medicolegal Autopsies, Consent for Medical Autopsies. Retrieved from <https://emedicine.medscape.com/article/1730552-overview>