~~ November 19, 2018 ~~

Comments from the American Society for Clinical Pathology on the Notice of Proposed Rulemaking Concerning Promoting Program Efficiency, Transparency, and Burden Reduction for the Medicare and Medicaid Programs

The American Society for Clinical Pathology (ASCP) is providing these comments in response to CMS's promulgation of the September 20 Notice of Proposed Rulemaking (NPRM) promoting program efficiency, transparency and burden reduction for the Medicare and Medicaid programs (CMS-3346-P). 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.

In its NPRM, CMS outlined a series of proposals to eliminate or modify existing Medicare regulations the Agency believes are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. The Agency states these proposals are needed to reduce requirements that impede quality patient care or that divert resources away from furnishing high quality patient care.

Among the Agency's proposals is one to eliminate 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. CMS asserts that the Medicare CoP requirement is "redundant" and that "more detailed, specific requirements regarding medical-legal investigative autopsies are required by individual state law." ASCP is strongly opposed to this change because autopsies are *critical* to ensuring quality patient care.

Without the performance of an autopsies, it is not possible to say *with certainty* what caused a patient's death. While other technologies may be used to identify cause of death, autopsies remain the gold standard and are an indispensable quality assurance tool for evaluating and improving medical care. Autopsies play an important role in the investigation and discovery of unspecified disease and in assessing the validity of new diagnostic or therapeutic modalities. As a result, much of today's medical knowledge and advances are based in large part from information obtained from autopsies.

In summarizing the benefits of autopsies, the Medicare Payment Advisory Commission (MedPAC) stated in its 1999 June Report:

> "Autopsies can be a tool for learning, playing a role in the advancement of medicine as a whole, the training of medical students, and the continuing education of physicians. They provide a means of determining diagnostic accuracy and can serve an important role in quality control. Researchers have noted that autopsy findings contributed to important medical breakthroughs in understanding diseases such as AIDS and Alzheimer's disease (Lundberg 1998). Autopsies can assist in evaluating the effectiveness of new drugs and treatments. They also can provide family members of the deceased with important information about hereditary diseases. Furthermore, they can help to improve the accuracy of public health statistics by providing a way to detect previously undiagnosed disease."

In that report, the Medicare Payment Advisory Committee added:

> "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 predeath clinical diagnoses between 35 percent and 47 percent of the time (Leape 1994, Lundberg 1998). One recent study found that 45 percent of autopsies revealed one or more undiagnosed causes of death, two-thirds of which were considered treatable (Nichols et al. 1998)."

In 2015, the National Academies of Medicine, Engineering, and Medicine (NASEM) conducted an investigation into medical errors and accurate diagnoses, and much of their work, findings and recommendations, depended 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 in. The report noted:

> "Diagnostic errors may cause harm to patients by preventing or delaying appropriate treatment, providing unnecessary or harmful treatment, or resulting in psychological or financial repercussions. It is estimated that 5 percent of U.S. adults who seek outpatient care each year experience a diagnostic error. *Postmortem examination research spanning decades has shown that diagnostic errors contribute to approximately 10 percent of patient deaths, and medical record reviews suggest that they account for 6 to 17 percent of adverse events in hospitals* (emphasis added).

Among NASEM's key recommendations was its call on HHS to encourage the performance of *more autopsies*.

Similarly, MedPAC has also recommended that HHS implement policies to increase the autopsy rate. MedPAC said 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" in its June 1999 report. MedPAC also urged increased reliance on "information derived from autopsies in health care quality improvement and error reduction initiatives."

One of ASCP's concerns with the CMS proposal is that *state laws requiring the performance of an autopsy are woefully insufficient and inconsistent and are not be not adequate to protect patient health*.

In preparing these comments, ASCP reviewed a Centers for Disease Control and Prevention (CDC) file on state laws concerning autopsies. The data provided 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. In fact, for only one of the 31 characteristics on which CDC reported data was there a majority of states (32) with an autopsy policy.[1]

The CDC file, Selected characteristic of deaths requiring autopsy, indicates that only six states have autopsy laws for cases of "suspicious/unusual/unnatural" death and only four states have adopted autopsy policies for cases of "unknown/unexplained" deaths. Just two states have policies concerning the performance of autopsies for deaths described as "sudden when in apparent good health." In addition, CDC's data indicates that only four states have policies concerning autopsies for "sudden unexplained infant death" (Sudden Infant Death Syndrome not suspected).

ASCP is also concerned that the enforcement of the CMS Medicare CoP autopsy policy and state autopsy laws may not be adequately followed or enforced. A 2011 article in ProPublica reported on one survey of autopsy performance that "found that 63 percent of hospitals in Louisiana performed [no autopsies] in a given year." It is hard to imagine that there weren't any deaths in any of the surveyed hospitals that would have necessitated an autopsy.

This data suggests that CMS's justification for eliminating its autopsy requirement is flawed. In the Agency's proposed rule, CMS states that its autopsy requirement is "redundant" and that "more detailed, specific requirements regarding medical-legal investigative autopsies are required by individual state law." Given the aforementioned data it is hard to see how CMS's autopsy requirement is "redundant" or that there are many states with "more detailed, specific requirements." Eliminating this requirement would appear to create sizable gaps that would further reduce the likelihood that autopsies are performed.

ASCP firmly believes that without more frequent use of autopsies, NASEM's warning becomes that much more concerning. 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 the autopsy rate erodes further, as it would if CMS eliminates the Medicare CoP autopsy requirement. This requirement does not "impede quality patient care or…divert resources away from furnishing high quality patient care." On the contrary, as noted by NASEM and MedPAC, autopsies, and by extension CMS's autopsy policy, embody the goals of safeguarding quality patient care, ensuring the efficient use of medical resources, and reducing the likelihood of medical errors.

Despite its importance to quality and the advancement of medical knowledge, pathologists, the best trained, best skilled and most knowledgeable professionals that perform autopsies, do not receive reimbursement for the autopsy work they perform. Neither Medicare, through the Physician Fee Schedule (PFS), nor private insurers provide reimbursement for time-consuming autopsy work. This lack of re-imbursement fuels other impediment that have led to sharp declines in the frequency of this service.

[1] 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."

As a result, we urge CMS to rescind its proposal to eliminate its Medicare CoP autopsy policy. Rather than eliminating the autopsy 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.

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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.