September 10, 2024

The Honorable Governor Janet Mills 1 State House Station Augusta, ME 04333

Dear Governor Mills,

The undersigned medical and specialty organizations represent physicians providing medical and surgical care for Maine patients every day. Our organizations write to strongly urge you to retain the Medicare physician supervision requirement that is currently followed by nearly all states in the Northeastern and the East Coast of the United States. A decision to "opt-out" of the physician supervision of nurse anesthetist's requirement would jeopardize patient safety and at the same time do nothing to increase access to care, save costs, or meet patients' overwhelming expectations for a physician to be responsible for their care.

Patient Safety at Risk

Maine has a safety net in place that ensures equitable care for all surgical patients by having a physician overseeing their anesthesia care. Removing physician supervision from anesthesia in surgery lowers the standard of care and jeopardizes patients' lives. Anesthesiology is the practice of medicine.

While anesthesiologists have increased the safety of anesthesia care dramatically over the century and half it has been available, it is still a potentially dangerous medical procedure. Pre-operative patient preparation and screening, administration of anesthesia, and management of potential complications is a complex and technically demanding medical process that requires physician supervision. Nurse anesthetists are qualified and important members of the anesthesia care team but do not have the medical education and training to replace a physician. Compared to physicians, nurse anesthetists have about half the education and one-fifth the hours of clinical training. There are no unbiased studies that show nurse anesthetists can ensure the same safety and outcomes in surgery as physician anesthesiologists. However, there is independent research published in the peer-reviewed journal *Anesthesiology* that shows that the presence of a physician anesthesiologist in surgery prevented 6.9 excess deaths per 1,000 cases in which an anesthesia-related or surgical complication occurred. Needlessly eliminating the State's safety net jeopardizes patient safety.

Recent real-life examples illustrate the anesthesia risks described in independent studies. The Modesto Bee, a California newspaper, recently ran a series of articles v,v,vi reporting on investigations the California Department of Public Health (CDPH) involving nurse anesthetists inappropriately practicing without physician clinical engagement at Stanislaus Surgical Hospital. CDPH stated the investigations were initiated in response to specific patient complaints. Subsequent, regulatory inspections of the hospital were highly critical of facility management of medical emergencies and indicated concerns about the use of nurse anesthetists in patient care. There were alarming findings regarding actual patient harm, and inspectors declared that the problems were serious enough to pose an immediate threat to patient safety. As a result of risks to patients, the hospital faced termination from the Medicare program and its Medicaid agreement unless approved corrective actions to the anesthesia care were implemented.

No Increase in Access to Care

Since 2016, six studies have been published in peer reviewed journals examining the relationship between opt-out and anesthesia access. All six published studies found that opt-out was not associated with an increase in access to anesthesia care. VIII, IX, X, XII The fifth, a 2021 Journal of Rural Health article, provided in part, "Given that we found no evidence that being in an opt-out state increases the odds of using CRNAs in hospitals, we contribute to the growing literature suggesting that states adopting the opt-out policy have not realized increased health care access or reduced health care costs."XIII The sixth study, from the 2023 Journal of Public Health, found "After CRNAs were granted practice independence, we find only modest (3%) reductions in anesthesiologist billing for CRNA supervision and no evidence of greater

use of CRNAs."xiii Also of note, the 2019 Graduate Nurse Demonstration Project which was mandated as part of the Affordable Care Act of 2010, found "ninety six percent of alumni who are [nurse anesthetists...] reported working in urban settings. This is not surprising, as [nurse anesthetists] may be more likely to work in urban settings with larger anesthesia departments..."xiv

No Financial Savings for Patients or the State

An opt-out similarly fails to save patients' or taxpayers' money. Medicare (and in a majority of states, Medicaid) pays the same for anesthesia care whether the service is provided by an anesthesiologist, an anesthesiologist medically directing a nurse anesthetist or certified anesthesiologist assistant, a nurse anesthetist supervised by the operating surgeon, or in those rare circumstances where it takes place, a nurse anesthetist practicing without physician supervision. The amount of the Medicare payment, no matter how it is allocated, is the same regardless of who provides the anesthesia care.

The Public wants Physician-Led Anesthesia Care

Finally, there is little support from the general public for an opt-out. Surveys repeatedly show patients want physicians in charge of their anesthesia care. In a recent American Medical Association survey, 91 percent of respondents said that a physician's years of medical education and training are vital to optimal patient care, especially in the event of a complication or medical emergency. Eighty-four percent said that they prefer a physician to have primary responsibility for the diagnosis and management of their health care. Ye In 2021, Forbes & Tate Partners conducted a study of Maine residents to ascertain their stance on physician led anesthesia care. When it comes to their care, Mainers overwhelmingly want physician led care, especially in invasive, serious procedures.

Opt-out is a failed policy experiment. It decreases patient safety in operating rooms and hospitals, it does not improve access to care, it does not save the state or patients money, and it ignores the public's preference for physician-led care. Beyond these critical factors, it is obvious that the standard for making such a sweeping change should be that there is clear and convincing evidence that it is safe to do so. No credible peer reviewed research can or has made that case.

We strongly encourage you to continue the important Medicare supervision patient safety standard for the people of Maine.

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- vii Stanislaus Surgical Hospital. Statement of Deficiencies and Plan of Correction. Department of Health and Human Services/Centers for Medicare and Medicaid Services. Survey Completed 2024/02/05. Available at: https://www.cdph.ca.gov/Programs/CHCQ/LCP/CalHealthFind/Pages/ASPEN_FEDERAL_2567.aspx?EventID=TRCF_12
- Sun EC, Miller TR, Halzack NM. In the United States, "Opt-Out" States Show No Increase in Access to Anesthesia Services for Medicare Beneficiaries Compared with Non-"Opt-Out" States. A&A Case Reports. 2016; 6(9):283-5.
- ^{ix} Sun EC, Dexter F, Miller TR. The Effect of "Opt-Out" Regulation on Access to Surgical Care for Urgent Cases in the United States: Evidence from the National Inpatient Sample. Anesthesia & Analgesia. 2016; 122(6):1983-91.
- * Sun EC, Dexter F, Miller TR, Baker LC. "Opt Out" and Access to Anesthesia Care for Elective and Urgent Surgeries among U.S. Medicare Beneficiaries. Anesthesiology. 2017; 126(3):461-71.
- xi Schneider JE, Ohsfeldt R, Li P, Miller TR, Scheibling C. Assessing the impact of state "opt-out" policy on access to and costs of surgeries and other procedures requiring anesthesia services. Health Econ Rev. 2017; 7(1):10.
- xii Feyereisen SL, Puro N, McConnell, W. Addressing provider shortages in rural America: The role of state opt-out policy adoptions in promoting hospital anesthesia provision. J Rural Health. 2021; 37(4):684-691.
- xiii Chen AJ, Munnich EL, Parente ST, Richards MR. Provider turf wars and Medicare payment rules. J. Public Econ. 2023; 218(C).
- xiv The Graduate Nurse Education Demonstration Project: Final Evaluation Report, Centers for Medicare and Medicaid Services. August 2019. https://innovation.cms.gov/files/reports/gne-final-eval-rpt.pdf (p.95).
- xv Baselice & Associates conducted a telephone survey on behalf of the AMA Scope of Practice Partnership between March 8-12, 2012. Baselice & Associates surveyed 801 adults nationwide. The overall margin of error is +/- 3.5 percent at the 95 percent level. Baselice & Associates conducted an internet survey of 802 adults on behalf of the AMA Scope of Practice Partnership, July 12-19, 2018. The overall margin of error is +/- 3.5 percent at the 95 percent confidence level.

ⁱ In addition to the CMS physician supervision requirement, Maine law requires, with limited exception for critical access and rural hospitals, that a nurse anesthetist is responsible and accountable to a licensed physician or dentist for aspects of anesthesia practice that require execution of the medical regimen as prescribed by that physician or dentist. Me. Rev. Stat. Ann. tit. 32, § 2211; 02-380-8 Me. Code R. § 1.

ii In 2000, the Institute of Medicine identified anesthesiology and its professional organizations as the leading example of systematic improvements in patient safety and quality of care. To Err is Human: Building a Safer Health System. Institute of Medicine. 2000.

iii Silber JH, Kennedy SK, Even-Shoshan O, Chen W, Koziol LFL, Showan AM, Longnecker DE: Anesthesiologist direction and patient outcomes. Anesthesiology 2000; 93: 152-a63.

^{iv} Carlson K. (2024, April 18). Stanislaus County hospital is removed from the Medicare program over health, safety issues. The Modesto Bee.

^v Carlson K. (2024, May 29). Complaints at Modesto hospital under investigation by California agency. What's the concern? The Modesto Bee.

vi Carlson, K. (2024, June 10). Modesto hospital shaken by California probe into anesthesia providers. What to know. The Modesto Bee.