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| COURT OF APPEALS, STATE OF COLORADO<br>101 West Colfax Avenue, Suite 800<br>Denver, CO 80202 | |
| Appeal from the District Court, City & County of Denver<br>Honorable Ann B. Frick, District Judge<br>Case No. 2010CV7731 | |
| **Plaintiffs-Appellants**: COLORADO MEDICAL SOCIETY, a Colorado nonprofit corporation, and THE COLORADO SOCIETY OF ANESTHESIOLOGISTS, a Colorado nonprofit corporation<br><br>**Defendant-Appellee**: JOHN HICKENLOOPER, in his official capacity as the Governor of Colorado<br><br>**Intervenors-Appellees**: COLORADO ASSOCIATION OF NURSE ANESTHETISTS; COLORADO NURSES ASSOCIATION; and COLORADO HOSPITAL ASSOCIATION | **▲COURT USE ONLY ▲** |
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| **BRIEF OF AMICUS CURIAE AMERICAN HOSPITAL ASSOCIATION IN SUPPORT OF APPELLEES** | |

## CERTIFICATE OF COMPLIANCE

I hereby certify that this amicus brief complies with all requirements of C.A.R. 28 and C.A.R. 32, including all formatting requirements set forth in these rules. Specifically, the undersigned certifies that:

1. The brief complies with C.A.R. 28(g).

   Choose one:

   X It contains 3,544 words.

   __ It does not exceed 30 pages.

2. The brief complies with C.A.R. 38(k).

   __ For the party raising the issue:

   It contains under a separate heading (1) a concise statement of the applicable standard of appellate review with citation to authority; and (2) a citation to the precise location in the record, not to an entire document, where the issue was raised and ruled on.

   X For the party responding to the issue:

   It contains, under a separate heading, a statement of whether such party agrees with the opponent's statements concerning the standard of review and preservation for appeal, and if not, why not.

s/ Christopher O. Murray
Christopher O. Murray

*[Original Signature on file at the offices of Hogan Lovells US LLP]*

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Comes now the American Hospital Association ("AHA"), and pursuant to C.A.R. 29 presents this amicus brief in support of Appellees. The Colorado Governor determined that it was in the best interest of Colorado's citizens to exercise the opt out for a Medicare requirement that a certified registered nurse anesthetist ("CRNA") administering anesthesia be supervised by a physician. The opt out came after the Governor conferred with the Colorado Medical Board and Colorado Board of Nursing about issues related to access to, and the quality of, anesthesia services in Colorado. The opt out was limited to Critical Access Hospitals and named rural general hospitals, both of which provide patient care in rural areas. The District Court granted a motion to dismiss in favor of the Governor. The Governor's efforts to ameliorate gaps in access to care for Coloradans living in rural parts of the State should be affirmed.

## STATEMENT OF THE ISSUE PRESENTED AND INTEREST OF AMICUS CURIAE AMERICAN HOSPITAL ASSOCIATION

AHA submits this amicus brief to address the following issue:

> Whether the District Court correctly dismissed Appellants' challenge to the Governor's decision to ameliorate gaps in access to care for Coloradans in rural parts of the State by permitting CRNAs to more fully utilize their professional training, after determining that physician supervision of CRNAs was not required by Colorado law.

AHA represents nearly 5,000 hospitals, health care systems, and networks, plus 42,000 individual members. AHA members are committed to improving the

health of communities they serve and to helping ensure that care is available to, and affordable for, all Americans. AHA educates its members on health care issues and advocates to ensure that their perspectives are considered in formulating health care policy.

This case is about the Governor's decision that it was in the best interest of Colorado's citizens, and consistent with Colorado law, to address the undisputable gap in access to care for individuals living in rural areas of the State by opting out of the Medicare CRNA physician supervision requirement. In Colorado and across the United States, seventy-two million Americans live in rural areas and depend upon the hospital serving their community as an important, and often only, source of health care. *See* AHA, *Trendwatch: The Opportunities and Challenges for Rural Hospitals in an Era of Health Reform* (Apr. 2011).[1] The nation's nearly 2,000 hospitals serving rural areas frequently serve as an anchor for their region's health-related services and provide the structural and financial backbone for physician practice groups, health clinics, and post-acute and long-term care services. *Id.*

[1] *Available at* https://aharesourcecenter.wordpress.com/2011/05/02/opportunites-and-challenges-for-rural-hospitals-in-an-era-of-health-reform/ (last visited Dec. 20, 2011).

Rural hospitals, like the Critical Access Hospitals and rural general hospitals to which the Governor's opt out applies, face a number of challenges due to their more remote locations, small size, limited workforce, and constrained financial resources. Demographic information about both the patient population and rural health care workers demonstrates some of these challenges. The rural hospital patient population is generally older, less healthy, less wealthy, and must travel greater distances to seek care with less access to reliable transportation, which can delay treatment and aggravate health problems. *Id.* The combined effect of an older age mix of the population and the greater poverty levels in rural areas make rural hospitals highly dependent on public programs like Medicare. Indeed, on average, 60% of gross revenue in rural hospitals comes from these public programs. *Id.* That fact means that reimbursement limitations for these programs have an especially significant impact on rural hospitals. *Id.*

There is also a growing shortage of health care workers that has affected rural areas more than urban or suburban areas. *Id.* This shortage increases the need for available health care workers to use the full extent of their professional training and capability, as permitted by state law. AHA has attested to the need to respond to workforce shortages, particularly with respect to rural communities. *See* Letter from AHA to Appropriations Subcomm. on Labor, Health & Human

Servs., and Educ. (May 20, 2011), *available at* http://www.aha.org/advocacy-issues/letter/2011/110523-let-pollack-rehberg-deLauro.pdf (last visited Dec. 20, 2011). Workforce issues are a key strategic priority for AHA. Over the last ten years, AHA has been acutely aware of and attentive to the critical importance of developing the workforce of the future. *See* AHA Commission on Workforce, *In Our Hands* (2002) (focused on hospital staff recruitment and retention); AHA Commission on Workforce, *Health Care Workforce: New Ways of Working in Hospitals* (2003) (a practical guide to use hospital staff skills and time more effectively); AHA Long-Range Policy Committee, *Workforce 2015: Strategy Trumps Shortage* (2009) (including recommendations for addressing workforce needs).

After proper consultation with the Colorado Medical Board and Board of Nursing, the Governor chose to make use of the latitude provided under the Medicare program to permit States to make full use of CRNAs without risking their hospitals being found ineligible for reimbursement. Governor Ritter exercised that latitude specifically for rural general and Critical Access Hospitals that face the challenges identified above. The opt out will improve access to health care for rural Coloradans. The Governor's choice—which, as Appellees explain, is fully consistent with Colorado law—should be upheld by this Court.

## STANDARD OF REVIEW

The appeal presents a pure question of law, which was preserved below and which this Court reviews *de novo*. *See Specialty Restaurants Corp. v. Nelson*, 231 P.3d 393, 397 (Colo. 2010).

## ARGUMENT

### I. The Federal Government Permits States To Make Full Use Of The Scope Of Practice That State Law Accords To CRNAs By Allowing States To Opt Out Of A Physician Supervision Requirement While Remaining Eligible For The Medicare Program.

The Medicare program has consistently permitted CRNAs to administer anesthesia. The only issue has been whether, and to what extent, CRNAs must be supervised by a physician in order to be eligible for Medicare reimbursement. From 1986 to 2001, Medicare program requirements for reimbursement required that CRNAs work "under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed." 51 Fed. Reg. 22,010, 22,049 (June 17, 1986) (final rule).[2] No explanation was given for the supervision

[2] The regulations have never required CRNAs to work under the direct medical supervision of an anesthesiologist. CRNAs have always been permitted to work under the "general supervision" of a surgeon who does not have any specialized training in anesthesiology. 54 Fed. Reg. 3,803, 3,807 (Jan. 26, 1989); *see also* 66 Fed. Reg. 4,674, 4,679 (Jan. 18, 2001) (final rule, subsequently withdrawn by amended final rule on Nov. 13 2001) ("Even under the current regulation CRNAs are not required to be under the supervision of an anesthesiologist; the operating physician can meet the rule's requirements.").

requirement when it was first proposed or when it was finalized. *See* 48 Fed. Reg. 299, 304 (Jan. 4, 1983) (proposed rule); 51 Fed. Reg. at 22,028 (final rule).

In the years after the 1986 supervision requirement took effect, advances in the safety of anesthesia prompted the federal government to reconsider whether physician supervision of CRNAs should be a requirement for Medicare reimbursement. In 1997, the federal government proposed repealing the physician supervision requirement entirely from the Medicare Program. *See* 62 Fed. Reg. 66,726, 66,740 (Dec. 19, 1997) (proposed rule).[3] Based on comments submitted in response to the proposed rule, CMS recognized that some states may have written their laws based on the assumption that Medicare would continue to require supervision of CRNAs. 66 Fed. Reg. 56,762, 56,762 (Nov. 13, 2001) (final rule). Changing course to eliminate the federal requirement could therefore "change supervision practices in [those] States without allowing [the] States to consider their individual situations." *Id.* CMS was concerned that if there had there been no Medicare supervision requirement, "States might have promulgated different laws or different monitoring practices." *Id.*

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[3] The Medicare program is regulated by the U.S. Department of Health and Human Services ("HHS"). The agency responsible for the Medicare program within HHS is now called the Centers for Medicare and Medicaid Services, or "CMS." To avoid confusion, this brief refers to both CMS and its predecessor agency, the Health Care Financing Administration, as CMS.

When it finalized the change in Medicare policy in 2001, CMS accordingly decided to give States the latitude to voluntarily opt out of the supervision requirement for the Medicare program—to the extent supervision was not required under state law—rather than eliminate the requirement altogether. *Id.* at 56,768-69. The motivation for this latitude was that anesthesia had become significantly safer and there was no evidence that physician supervision of CRNAs resulted in better patient outcomes. *See* 66 Fed. Reg. at 4,678-79 (anesthesia mortality rate declined from two deaths per 10,000 anesthetics administered in the early 1980s to one death per 200,000–300,000 anesthetics administered in 1999); *id.* at 4,675 (CMS concluded that there is "no compelling scientific evidence that an across-the-board Federal physician supervision requirement for CRNAs leads to better outcomes"). Indeed, CMS was worried that the supervision requirement "could potentially limit development of new practice models of anesthesia delivery, or interfere with progress in promoting practices that improve patient outcomes." *Id.* at 4,682. In light of the wide variations in patient types, surgical procedures, technologies, provider settings, and other factors unique to each case, CMS determined that an across-the-board federal requirement was simply "not sensible." *Id.* at 4,679.

The final rule promulgated by CMS in 2001 therefore sought to enable States to determine the appropriate scope of practice for CRNAs by replacing the Medicare program's supervision requirement with an optional requirement, dependent on state law. "Under this final rule, State laws will determine which professionals are permitted to administer anesthetics and the level of supervision required, recognizing a State's traditional domain in establishing professional licensure and scope-of-practice laws." 66 Fed. Reg. at 56,762. CMS explained how the opt out worked: the governor of a State, in consultation with the State's Boards of Medicine and Nursing, could exercise an option of exemption from the physician supervision requirement. *Id.* at 56,763. The opt-out was designed to "give States the flexibility to improve access and address safety issues." *Id.*[4] And by requiring that a governor consult with both the Boards of Medicine and Nursing, CMS felt that it would "ensure appropriate involvement of parties on both sides of the issue." *Id.* at 56,764. As CMS recognized, "the particular factors that are pertinent in reaching a sound policy decision will invariably vary from State to State (*for example, access to anesthesia services in rural areas*)." *Id.* (emphasis added).

[4] Even if a State exercises the opt out, CMS reiterated that individual hospitals could choose to retain physician supervision of CRNAs if they wished to. *Id.* at 56,765 ("The final rule would not require hospitals under any circumstances to eliminate physician supervision if they deem this appropriate.").

The 2001 rule, which remains in effect today, thus moves decision-making authority away from the national level and authorizes a governor, in consultation with the Boards of Medicine and Nursing, to determine a policy for CRNA's scope of practice that best serves each State and is consistent with State law. The 2001 rule was specifically designed to ensure that "those closest to, and who know the most about, the health care delivery system are accountable for the outcomes of that care." *Id.* at 56,765.

The opt-out rule has now been in place for a decade. CMS has never reconsidered or second-guessed it. To the contrary, CMS has consistently reaffirmed its commitment to eliminating needless structure and process requirements in health care delivery systems. In one recent rulemaking, for example, CMS has proposed a *further* expansion of the scope of practice for non-physician professionals. 76 Fed. Reg. 65,891, 65,894 (Oct. 24, 2011) (proposed rule) (proposed revisions would permit hospitals to "increase the number of practitioners who could perform various functions and duties" and thereby "allow hospitals to move forward in new ways to improve patient care"). This continued push for flexibility demonstrates that CMS is satisfied that allowing States and hospitals to have increased latitude in using advanced practice nurses like CRNAs

can improve access while adequately addressing safety issues like quality of care and patient outcomes.

## II. Sixteen States Have Opted Out Of The Physician Supervision Requirement Without Reporting Any Adverse Consequences.

Sixteen States have opted out of the federal supervision requirement since the option first become available in 2001: Iowa (in 2001); Nebraska (in 2002); Idaho (in 2002); Minnesota (in 2002); New Hampshire (in 2002); New Mexico (in 2002); Kansas (in 2003); North Dakota (in 2003); Washington (in 2003); Alaska (in 2003); Oregon (in 2003); Montana (in 2004); South Dakota (in 2005); Wisconsin (in 2005); California (in 2009); and Colorado (in 2010). None of those states have reported any dissatisfaction with its opt-out experience. And although the federal regulations expressly permit a State to withdraw its opt out, only Montana has (briefly) exercised that option. A new governor withdrew the State's opt out in May 2005, before restoring it one month later in June 2005. *See* Rachel Fields, *16 States That Have Opted Out of Physician Supervision of Anesthesia Rule*, Becker's ASC Review (Oct. 26, 2010).[5]

The experience of these States over a decade demonstrates that choosing to opt out of the physician supervision requirement does not adversely affect quality

[5] *Available at* http://www.beckersasc.com/anesthesia/16-states-that-have-opted-out-of-physician-supervision-of-anesthesia-rule.html (last visited Dec. 20, 2011).

of care or patient outcomes. A 2003 letter from then-Governor of Iowa Tom Vilsack to then-Governor of Colorado Bill Owens summarizes that State's experience well. The decision to opt out, Governor Vilsack wrote, has been a "remarkable success" that has "resulted in an improved outlook for rural Iowa healthcare." Letter from Gov. Thomas Vilsack to Gov. Bill Owens (July 21, 2003).[6] Governor Vilsack noted that "[a]bsolutely no reports have been made of problems or changes in the quality of care provided." *Id.* Quite to the contrary, the Iowa Department of Public Health and the Iowa Board of Nursing had informed the Governor that "the quality of care given by CRNAs has never been higher." *Id.* And hospital administrators, physicians, and healthcare organizations wrote to the Governor to praise "the overwhelming success of the opt-out." *Id.*

## III. Opting Out Of The Physician Supervision Requirement Allows States To Improve Access To Health Care In Underserved Rural Areas.

Colorado's opt out is limited to Critical Access Hospitals[7] and specified rural general hospitals. Like Colorado, most of the other opt-out States have large areas of rural populations. These are not coincidences. Rural areas of the United States have great difficulty recruiting and retaining anesthesiologists and other

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[6] *Available at* http://www.aana.com/advocacy/stategovernmentaffairs/Documents/ia%20gov.pdf (last visited Dec. 20, 2011).

[7] Critical Access Hospitals offer 24-hour emergency services in remote areas. *See* 42 C.F.R. § 485.610(b)-(c).

physicians, and they consequently suffer from acute physician shortages. *See* Council on Graduate Medical Education, *Tenth Report: Physician Distribution and Health Care Challenges in Rural and Inner-City Areas* 11 (Feb. 1998) (shortage of physicians in rural areas is "one of the few constants" in the U.S. health care system). Approximately twenty percent of Americans live in rural areas, yet only nine percent of American physicians practice in rural areas. *Id.* Colorado alone has dozens of federally-designated "Health Professional Shortage Areas," which lack a sufficient number of physicians and other health professionals to meet the health care needs of residents. *See* Health Res. & Servs. Admin., U.S. Dep't of Health & Human Servs., *Designated Primary Care Health Professional Shortage Areas* (as of September 1, 2011), *available at* http://bhpr.hrsa.gov/shortage/hpsas/updates/09012011primarycarehpsas.html#Colorado (last visited Dec. 20, 2011).

Anesthesiologists are in particularly short supply. According to the President of the American Society of Anesthesiologists, there is a nationwide shortage of anesthesiologists. Rachel Fields, *Top Challenges for Anesthesiologists: 5 Thoughts From ASA Incoming President Dr. Jerry Cohen*, Becker's ASC Review (July 20, 2011);[8] *see also* RAND Corp., *An Analysis of the*

[8] *Available at* http://www.beckersasc.com/anesthesia/the-top-challenges-for-anesthesiologists-5-thoughts-from-asa-incoming-president-dr-jerry-cohen.html (last visited Dec. 20, 2011).

*Labor Markets for Anesthesiology* 71-72 (2010) (shortage of anesthesiologists is likely to persist through 2020). And that shortage is even more pronounced in rural areas. Of the currently practicing anesthesiologists, ninety-five percent practice in urban areas. *See* RAND Corp., *Is There a Shortage of Anesthesia Providers in the United States?*, at 2-3 (2010).[9] Rural health facilities are consequently much less likely to employ anesthesiologists than their peer facilities in urban areas. RAND Corp., *An Analysis of the Labor Markets*, *supra*, at 71.

This broad mismatch between supply and demand for medical services "threaten[s] health care delivery in many rural communities in the United States." Donald E. Pathman *et al.*, *Retention of Primary Care Physicians in Rural Health Professional Shortage Areas*, 94 Am. J. Pub. Health 1723, 1723 (2004). Among other things, the shortage of rural physicians increases the cost of care for hospitals in those areas and impedes patients' access to care. *See The Physician Shortage Crisis in Rural America: Who Will Treat Our Patients?: Hearing Before the S. Comm. on Health, Educ., Labor, and Pensions*, 110th Cong. 76 (2007) (report of the Alaska Physician Supply Task Force). These adverse consequences fall on a particularly vulnerable population, for rural residents tend to be older, have lower incomes, and suffer from higher rates of chronic illness than their urban

[9] *Available at* http://www.rand.org/pubs/research_briefs/RB9541.html (last visited Dec. 20, 2011).

counterparts. AHA, *Trendwatch*, *supra*. Moreover, because anesthesia services are typically provided in connection with other medical procedures, the shortage of anesthesiologists has a ripple effect across other medical disciplines.

CRNAs have the professional training needed to alleviate the lack of access to physician-supervised anesthesia care. While Colorado has a shortage of anesthesiologists, it has a surplus of CRNAs. *See* RAND Corp., *Is There a Shortage of Anesthesia Providers*, *supra*, at 2. And because CRNAs are more likely than anesthesiologists to work in rural areas, they have become "a particularly important labor source in rural areas." RAND Corp., *An Analysis of the Labor Markets*, *supra*, at 3, 17. Indeed, in the States that have opted out of the federal physician supervision requirement, CRNAs "tend to be the sole anesthesia providers in the vast majority of rural hospitals . . . ." Takashi Matsusaki & Tetsuro Sakai, *The Role of Certified Registered Nurse Anesthetists in the United States*, 25 Journal of Anesthesia 734, 737 (2011). They allow those rural hospitals to offer "surgical and obstetrical services, trauma stabilization, and interventional diagnostic and pain management capabilities" that might not otherwise be available. *Id.*

CMS had these features of the health care labor market in mind when it instituted the opt out. The new rule was designed in part to "give States the

flexibility to improve access" to health care in rural areas. 66 Fed. Reg. at 56,767. As CMS recognized, nurse anesthetists have "increased access to anesthesia care, and thereby, access to medical and surgical procedures that would likely be unavailable if not for a practitioner qualified to administer anesthesia." 66 Fed. Reg. at 4,682. The new rule encourages that trend by allowing States and hospitals to find new ways to deliver anesthesia services. Indeed, at least one governor concluded that choosing *not* to opt out could "severely limit the ability of rural hospitals to treat emergencies and provide other services requiring anesthesia care to Medicare patients." Letter from Gov. Frank Murkowski to Thomas Scully (Sept. 17, 2003). [10]

## IV. Recent Research Confirms That Opting Out Facilitates The Cost Effective Provision Of Anesthesia Services Without Adversely Affecting Quality Of Care Or Patient Outcomes.

The passage of time has only reinforced the federal government's assessment from 2001 that removing the physician supervision requirement would not affect quality of care or patient outcomes. A study published last year reviewed data from 1999 to 2005 to determine whether the federal opt out provision had led to more inpatient deaths or complications. *See* Brian Dulisse & Jerry Cromwell, *No Harm Found When Nurse Anesthetists Work Without*

[10] *Available at* http://www.aana.com/advocacy/stategovernmentaffairs/Documents/alaska.pdf (last visited Dec. 20, 2011).

*Supervision By Physicians*, 29 Health Affairs 1469 (2010). The authors compared outcomes in States that had opted out to outcomes in States that had not opted out, controlling for various factors. *See id.* at 1470–71. They found no increase in adverse outcomes in either opt-out States or non-opt-out States; in fact, mortality rates declined in both groups of States. *Id.* at 1474. Nor did the data suggest that patients are exposed to increased surgical risk when CRNAs work without physician supervision. *See id.* (rate of adverse outcomes for patients treated by CRNAs in opt-out States "did not vary greatly between the period before opting out and the period after"). In other words, "patient safety was not compromised by the opt-out policy." *Id.* at 1475.

Other recent studies support the basic findings of the *Health Affairs* study. In a 2009 article, for example, two researchers concluded that obstetrical outcomes are not systemically poorer in hospitals that use only CRNAs, or a combination of CRNAs and anesthesiologists, compared to hospitals that use only anesthesiologists. *See* Jack Needleman & Ann F. Minnick, *Anesthesia Provider Model, Hospital Resources, and Maternal Outcomes*, 44 Health Services Research 464 (2009). An earlier study reached essentially the same conclusion based on data from the State of Washington. *See* Daniel C. Simonson *et al*., *Anesthesia Staffing and Anesthetic Complications During Cesarean Delivery: A Retrospective*

*Analysis*, 56 Nursing Research, Jan.-Feb. 2007, at 15 ("Analysis of the incidence of anesthetic complications in 134,806 cesarean sections over 12 years suggests that hospitals that utilize CRNAs to provide their obstetrical anesthesia have no difference in rate of obstetrical anesthesia complications from those that use anesthesiologists.").

The insurance markets also seem to be confident that CRNAs are able to deliver anesthesia safely. As the American Association of Nurse Anesthetists has documented, premiums for CRNA professional liability insurance decreased 39% between 1988 and 2004—a drop that is particularly impressive in light of the sharp upward trend in premiums for other types of professional liability insurance. *See* Am. Ass'n of Nurse Anesthetists, *Quality of Care in Anesthesia* 14, 38–39 (2009). Finally, research has confirmed what is obvious to most observers: It is more cost-effective for CRNAs to work independently than to work under the supervision of an anesthesiologist. *See* Paul F. Hogan *et al*., *Cost Effectiveness Analysis of Anesthesia Providers*, 28 Nursing Economics 159, 166, 168 (2010).

This new research merely confirms what was evident to the federal government many years ago: Health care providers are well-positioned to determine what anesthesia delivery arrangements will best serve the local population. Where a governor, in consultation with the Boards of Medicine and

Nursing, determines that allowing CRNAs to administer anesthesia without requiring physician supervision is in the best interests of the State and consistent with State law, that exercise of the governor's discretion should be upheld. That is precisely what happened here, and therefore, the District Court's judgment in this matter should be affirmed .

## CONCLUSION

For the foregoing reasons, and those argued by Defendant-Appellee and Intervenors-Appellees, AHA respectfully requests that this Court affirm the judgment of the District Court in this matter.

December 21, 2011

Respectfully submitted,

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