



# IMAGINING IN TIME

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## Achieving the Opt Out for Medicare Physician Supervision for Nurse Anesthetists

*With California's July 2009 opt-out from the Medicare physician supervision requirement for nurse anesthetists, 15 states have now opted out since 2001. The work of the American Association of Nurse Anesthetists (AANA) that led to the supervision opt-out rule being implemented has a long history. Beginning in 1994, when the Health Care Financing Administration (HCFA) first proposed deferring to the states on the supervision*

*issue, the AANA worked for 7 years with HCFA and members of Congress to lay the groundwork for the opt-out rule that ultimately enabled the California governor's recent action.*

**Keywords:** Health Care Financing Administration (HCFA), Centers for Medicare & Medicaid Services (CMS), opt out, physician supervision.

### Beginnings: 1994-1997

With the inauguration of President Bill Clinton in 1993, healthcare reform became a priority of the administration, and part of the reform included legislation that would have an impact on the practice of nurse anesthetists. On April 25, 1994, Representative Mike Kreidler (D-WA) introduced H.R. 4291 that sought to eliminate 3 existing Medicare barriers to the practice of Certified Registered Nurse Anesthetists (CRNAs). One of these was Medicare's hospital and ambulatory surgical center rule that CRNAs had to be supervised by a physician; Kreidler's bill sought to defer the matter to the states instead. A few months later Senator Kent Conrad (D-ND) introduced S. 2310, the companion bill to H.R. 4291. The American Association of Nurse Anesthetists (AANA) began a public relations campaign that emphasized grassroots lobbying support for the bills—an effort that would continue throughout the coming years.

While the Senate adjourned in October 1994 without passing health-care reform, AANA received draft language from the Health Care

Financing Administration (HCFA, currently called the Centers for Medicare & Medicaid Services, or CMS), which contained revisions to the Medicare hospital conditions of participation, eliminated physician supervision of nurse anesthetists, and deferred the matter to state law. Although HCFA would repeatedly postpone the publication of the proposed rule, AANA continued to work with HCFA in 1995 and 1996. AANA finalized its Medicare reform recommendations to the 104th Congress at the Government Relations Workshop in Arlington, Virginia, in May 1995; one of the recommendations was the deferral of supervision to the states.

On September 16, 1995, Senator Conrad introduced S. 1263, the Medicare Services Reform Act, with bipartisan support from Senators Larry Pressler (R-SD), Daniel Inouye (D-HI), and Strom Thurmond (R-SC). The bill addressed issues relating to the lack of reimbursement when an anesthesiologist and a CRNA work jointly on one case and would defer to state law on the issue of physician supervision. Similar legislation was introduced in the House

of Representatives. In order to have the reimbursement mechanism move forward, it was necessary to leave out the language dealing with supervision; however, HCFA indicated it would address this issue later in the year as part of an overhaul of the Medicare conditions of participation. The reimbursement practice ratio continued as AANA's top legislative priority in 1996.

Supervision returned as one of the top priorities in AANA's legislative agenda in 1997; AANA wanted to find a sponsor for legislation to remove supervision and worked with 2 consulting firms to try to include a provision in the Medicare reform package. AANA began a grassroots campaign and contacted more than 11,000 CRNAs to urge calls and letters to key members of congressional committees. Later in the year, AANA dropped its legislative pursuit in favor of having HCFA deal with the issue.

### 1997 Proposed Rule

On December 19, 1997, HCFA issued a proposed rule in the *Federal Register*.<sup>1</sup> Included was a provision

removing the physician supervision requirement for nurse anesthetists and deferring the decision to the states. The rule:

...would remove the federal requirement that in anesthesia cases involving Medicare patients nurse anesthetists must be supervised in order for hospitals to be reimbursed for the nonanesthesia portion of the patients' care. Currently for nurse anesthetists themselves to be reimbursed, Medicare does not require physician supervision.<sup>2</sup>

The rule began a period of intensive work by the AANA to ensure that the supervision requirement would be removed. Mailings from AANA President Scott Foster, CRNA, PhD, were sent in January and March 1998 urging members to write to HCFA in support of the proposed rule that "justifiably reflects the government's recognition and trust in the profession of nurse anesthesia."<sup>3</sup> AANA's ad campaign began with the "Rest Assured..." ad that appeared in the February 13, 1998, issue of *USA Today* and assured seniors of the safety of nurse anesthesia care.

Nursing organizations took up the charge as they wrote in support of the proposed rule. American Nurses Association President Argene Carswell, RN, JD, wrote that the proposed rule would "remove cumbersome, restrictive, burdensome, and anti-competitive requirements for physician supervision" that have "served no demonstrated or practical purpose in protecting patient safety."<sup>4</sup>

The 60-day comment period ended, but bills that could nullify the proposal were proposed in both houses of Congress. Senator Lauch Faircloth (R-NC) introduced S. 1811 and Representative Dave Weldon (R-FL), a physician, introduced H.R. 3629. Both bills sought to prohibit HCFA from implementing any rule that would have the effect of removing the physician supervision requirement. The bills would require a study that would cost \$15 million according to the American Society of Anesthesiologists.<sup>5</sup>

Figure 1. AANA's "Take a Deep Breath" ad in 1999

In anticipation of Congress reconvening on September 1, 1998, the Public Relations Department and the Federal Government Affairs Office collaborated on an aggressive campaign to defeat the Faircloth amendment. A full-page, four-color ad with the headline "Take a Deep Breath and Count Backwards from \$15 Million..." (Figure 1) ran in the Washington, DC, papers, and a black and white version appeared in local newspapers to target senators from particular states. An editorial by AANA President Linda Williams, CRNA, JD, titled "Whatever Happened to States Rights?" was distributed to 604 newspapers, and a 60-second radio spot using copy from the print ad aired on 2 radio stations in Washington, DC.

Proposed rules S. 1811 and H.R. 3629 were not enacted; S. 1811 had only 1 cosponsor in the 100-member Senate, and H.R. 3629 had 25 cosponsors in the 435-member House of Representatives. Faircloth tried to attach his bill to the Labor-Health and Human Services

(Labor-HHS) appropriations legislation in the Senate. When that was unsuccessful, he moved to have a study required before HCFA could finalize the rule. That too failed. In the end, the Labor-HHS appropriations were wrapped up in the omnibus spending bill approved by Congress in the final hours of the congressional session. It included nonbinding report language urging that the Secretary of Health and Human Services base keeping or changing the current supervision requirement on outcomes data, and that the Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality) work with HCFA to design an outcomes-based research approach. While the bill was being considered, several senators engaged in a colloquy that interpreted that language of the conference report. They stated that the language was not binding on HCFA, that nothing prevented HCFA from moving forward to repeal physician supervision of CRNAs, and that no further stud-

ies were required as a matter of law. More than 100 members of Congress wrote to HCFA supporting the rule repealing physician supervision of nurse anesthetists.

On February 9, 1999, Congressmen David Weldon (R-FL) and Gene Green (D-TX) introduced legislation to stop the proposed rule. H.R. 632 (the Safe Seniors Assurance Study Act of 1999), would mandate HCFA to conduct a new study of anesthesia outcomes, and delay or stop the rule from moving forward. As previously noted, such a comprehensive study would cost an estimated \$15 million. A few weeks later, Representative Jim Nussle (R-IA) introduced H.R. 804, The Access to Anesthesia Services Act. This bill would require HCFA to defer the issue of supervision to the states as of January 1, 2000, and help patients in rural areas obtain access to anesthesia care.

AANA issued a press release, "Anesthesia Legislation Plays on Fears of Medicare Patients," in response to the Weldon/Green bill. It highlighted the cost of the study as well as previous studies that found no difference in outcomes by type of provider, including the Minnesota Department of Health<sup>6</sup> study and an examination of anesthesia outcomes by the Centers for Disease Control<sup>7</sup> (CDC, now the Centers for Disease Control and Prevention). The latter concluded morbidity and mortality rates were too low to warrant a multimillion dollar nationwide study.

In April, companion legislation to both bills was introduced in the Senate. Senators Kent Conrad (D-ND), Larry Craig (R-ID), and Byron Dorgan (D-ND) introduced S. 866, the Anesthesia Services Preservation Act of 1999, which would have directed HCFA to issue a final rule repealing the Medicare mandate for physician supervision of CRNAs, permitting the states to decide the issue. Senators Mike DeWine (D-OH) and Harry Reid (D-NV) proposed companion legislation (S. 818) to the Weldon bill, which

would have directed HCFA to undertake an outcomes study. Even though HFCA reported that it had no plans to address the supervision issue in the near future because of other pressing issues, such as Y2K compliance (year 2000 problem) in the Medicare system, both bills continued to gather supporters.

AANA disseminated the results of a telemarketing survey conducted by Wirthlin Worldwide, McLean, Virginia, that found 88% of Medicare patients would be comfortable if their surgeon chose a nurse anesthetist. Almost two-thirds indicated it was acceptable if the nurse anesthetist was not supervised by the surgeon but worked collaboratively with the surgeon.<sup>8</sup>

The second session of the 106th Congress was set to resume on January 24, 2000. Though neither bill had moved in committee, the supervision issue was addressed in other measures. The Senate Labor-HHS appropriations bill included report language that "recognized the balanced approach taken by HCFA on this issue in its proposed rule"<sup>9</sup> and urged HCFA to move forward and issue a final rule repealing physician supervision of CRNAs and permitting the states to decide the issue. The Balanced Budget Refinements Conference report included nonbinding language that provided "HCFA with the authority whether to consider additional outcomes or move forward based on existing data and issue a final rule."<sup>9</sup>

On March 9, 2000, HCFA informed AANA that it would remove the federal supervision requirement and that the final rule was expected to be published in the *Federal Register* in June. In response, Senator Mike DeWine convened a hearing in the Senate Judiciary Subcommittee on Antitrust, Business Rights, and Competition on June 8 regarding competition between nurse anesthetists and anesthesiologists and the proposed HCFA rule. While

DeWine was a sponsor of S. 818, the Judiciary subcommittee did not have jurisdiction over the supervision issue, as S. 818 and S. 866 had been referred to the Finance Committee. Testifying on behalf of the AANA were President Jan Stewart, CRNA, ARNP, and Michael Fallacaro, CRNA, DNS; for the anesthesiologists, former president of the American Society of Anesthesiologists Ellison Pierce, MD, and Jeffrey Silber, MD. DeWine's questions focused on the Silber et al study<sup>10</sup> and whether it had any significance to the supervision issue. Once again, AANA urged members to write letters of support and indicated that letters were also needed from hospital administrators, surgeons, nurses, other health professionals, and seniors.

### January 18 "Final" Rule

On January 18, 2001, a final rule was published in the *Federal Register*<sup>11</sup> that removed the supervision requirement and deferred to the states on the issue. The rule would take effect in 60 days on March 19. The rule meant that hospitals, critical access hospitals, and ambulatory surgery centers would be able to receive reimbursement from Medicare without requiring surgeons or other physicians to supervise nurse anesthetists. This was consistent with the current Medicare rule, implemented in 1989, that enabled nurse anesthetists themselves to be directly reimbursed by Medicare without a physician supervision requirement. Seniors would be cared for under the same rules and regulations that apply to all other anesthesia patients in their states.

In the rule, HCFA found that there was "no compelling scientific evidence that an across-the-board federal physician supervision requirement for CRNAs leads to better outcomes."<sup>11</sup> On the Silber et al study, HCFA said that it was not relevant "because it did not

study CRNA practice with and without physician supervision,” and HCFA further stated that it disagreed with the study’s “apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs.”<sup>11</sup>

On January 20, 2001, the incoming George W. Bush Administration announced a 60-day blanket moratorium on implementation of all regulations published in the final days of the Clinton Administration that had not yet taken effect. Tommy Thompson, the new Secretary for Health and Human Services, announced that the review could delay the effective dates by up to 60 days. Thompson had until mid-March to determine whether or not to delay the rule. AANA met with Thompson and his staff on February 23 and urged the 107th Congress to leave the regulation alone.

Notice was published in the *Federal Register*<sup>12</sup> that the effective date of the rule would be delayed by 60 days; the new effective date would be May 18. Senator Mike DeWine and Representative Dave Weldon introduced yet more legislation—S. 332 and H.R. 716—that sought to overturn the supervision rule, institute a multiyear study of comparative outcomes in anesthesia care, and mandate 3 federal scope-of-practice restrictions against CRNAs.

Then on May 18, HCFA published a 180-day delay for the supervision rule in the *Federal Register*,<sup>13</sup> along with a notice that it would propose a new rule very soon. The January 18 rule was now delayed for another 180 days with a new effective date of November 18, and the time would be used for HCFA to accept public comments and explore alternatives for implementation.

### July 5 Proposed Rule

The newly renamed Centers for Medicare & Medicaid Services (CMS,

formerly HCFA) published a proposed rule in the July 5, 2001 *Federal Register*<sup>14</sup> that reflected the notice of May 18. Instead of the blanket removal of supervision, states would be allowed to seek an exemption, or opt out, from the federal supervision requirement. To do this, the governor would need to consult with the state boards of medicine and nursing, determine that an exemption would be in the best interests of the citizens of the state, and determine that an exemption would be consistent with the state’s laws. The governor would notify CMS in writing of the state’s intention to opt out, with the exemption taking effect immediately. However, a governor would also have the ability to remove the exemption by sending written notification to CMS. The rule further proposed that the Agency for Healthcare Research and Quality, with input from CMS and other stakeholders, design and conduct a prospective study or monitoring effort to assess outcomes of care related to CRNA practice and involvement. One possible monitoring effort would be the creation of a voluntary CRNA registry. AANA urged members to send letters to their representatives, senators, and CMS. In AANA’s comments on the proposed rule, President Deborah Chambers, CRNA, MHSA, urged CMS to revert to the January 18, 2001 rule that deferred the matter to the states.

CMS set a deadline of November 14 for publication of the final rule. The rule was to be reviewed by HHS Secretary Tommy Thompson, CMS Administrator Tom Scully, the White House’s Office of Management and Budget, the President’s White House staff, and perhaps the President himself. In a report that accompanied the fiscal year 2002 Labor-HHS-Education Appropriations bill (S. 1536, S. Report 107-84), the Senate Appropriations Committee acknowledged that there were concerns with the Bush Administration’s

July 5 rule. The report urged Secretary Thompson to take the differing views of the interested parties into consideration before issuing a final rule. Meanwhile, Medicare staff members were reviewing tens of thousands of comments received from those on both sides of the issue.

### November 13 Final Rule

The final rule, published in the November 13, 2001, issue of the *Federal Register*,<sup>15</sup> retained the Medicare mandate on physician supervision of CRNAs while establishing an opt-out process for state governors. The rule took effect upon publication. In response, Chambers said, “We believe Medicare got it right the first time,”<sup>16</sup> in reference to the January 18 rule. Medicare is on record for having supported almost all of AANA’s arguments on the issue including its statement in the January 18 rule that anesthesia is not solely the practice of medicine.

### State Opt Outs

Now that supervision was deferred to the states, work began to encourage governors to opt out. Iowa became the first state when Governor Thomas Vilsack (Figure 2) sent a letter to CMS on December 12, 2001. In his letter, Vilsack noted that CRNAs are the exclusive providers of anesthesia services in 91 of the state’s 118 hospitals and that the opt out ensures access to anesthesia care.<sup>17</sup> Nebraska, Idaho, and Minnesota soon followed with 2 additional states opting out in 2002, 5 in 2003, 1 in 2004, and 2 in 2005 (Table). In July 2009, California became the 15th state to opt out.

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**Figure 2.** William Miller, CRNA (left) and Lieutenant Governor Sally Pederson with Iowa Governor Thomas Vilsack as he signs the opt-out letter in 2001

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State	Opt-out date
Iowa	December 2001
Nebraska	February 2002
Idaho	March 2002
Minnesota	April 2002
New Hampshire	June 2002
New Mexico	November 2002
Kansas	March 2003
North Dakota	October 2003
Washington	October 2003
Alaska	October 2003
Oregon	December 2003
Montana	January 2004
South Dakota	March 2005
Wisconsin	June 2005
California	July 2009

**Table.** Timeline of State Opt Outs

16. Administration puts politics before patients; implements cumbersome anesthesia care rule [press release]. Park Ridge, IL: American Association of Nurse Anesthetists; November 13, 2001.
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**ACKNOWLEDGMENTS**

The author would like to thank Kathy Koch, MLIS, CA, AANA archivist-librarian, and Frank Purcell, BS, AANA senior director, Federal Government Affairs, Washington, DC, for their assistance with this column.