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ABSTRACT In 2001 the Centers for Medicare and Medicaid Services (CMS) allowed states to opt out of the requirement for reimbursement that a surgeon or anesthesiologist oversee the provision of anesthesia by certified registered nurse anesthetists. By 2005, fourteen states had exercised this option. An analysis of Medicare data for 1999–2005 finds no evidence that opting out of the oversight requirement resulted in increased inpatient deaths or complications. Based on our findings, we recommend that CMS allow certified registered nurse anesthetists in every state to work without the supervision of a surgeon or anesthesiologist.

Surgical anesthesia in the United States is administered by both anesthesiologists and certified registered nurse anesthetists (CRNAs). For almost 150 years, these nurses were the dominant providers of anesthesia services, but by 1986 the rapid influx of physicians into the specialty resulted in a greater number of anesthesiologists who practiced alone or in a team arrangement with nurse anesthetists.^{1,2} Even so, 37,000 certified registered nurse anesthetists provide thirty million anesthetics annually in the United States and represent two-thirds of anesthetists in rural hospitals.³

Background On The Issue

Until recently, the Centers for Medicare and Medicaid Services (CMS) reimbursement rules for anesthesia providers prohibited payments to certified registered nurse anesthetists who administered anesthesia in the absence of physician supervision. This supervision could be provided by either an anesthesiologist or the surgeon,⁴ although surgeons now largely defer to anesthetists at the operating table during the administration of anesthesia and immediately after surgery.

In December 1997, CMS published a proposed rule to, in the words of the final version, “let State law determine which professionals would be permitted to administer anesthetics, and the level of supervision required for practitioners [seeing Medicare patients] in each category.”⁵ The agency later reported basing its decision on a “lack of evidence to support...[the] requirement for [surgeon or anesthesiologist] supervision of Certified Registered Nurse Anesthetists.”⁶

It should be noted that except for the extra training that anesthesiologists receive in medical school and residency in specialties other than the direct provision of anesthesia, both certified registered nurse anesthetists and anesthesiologists undergo similar classroom and clinical training in anesthesia care.⁷

Anesthesiologists opposed the proposed rule, arguing that they provide anesthesia care superior to that of certified registered nurse anesthetists,^{2,8} even though adverse events related to anesthesia are rare regardless of the provider.^{5,9–11} The final CMS rule of November 2001 maintained physician supervision of nurse anesthetists “unless the governor of a State, in consultation with the State’s Boards of Medicine & Nursing, exercises the option of exemption from this requirement” through a written request

signed by the governor.⁶

As of 1998, eighteen states permitted certified registered nurse anesthetists to practice independently of any physician,¹² although for reimbursement purposes, Medicare still required physician supervision at least by the surgeon if not by an anesthesiologist.⁶ By 2005, fourteen governors in mostly rural states¹³ had submitted written requests to Medicare and opted out of the supervised anesthesia requirement. Solo practice by certified registered nurse anesthetists is especially important in rural areas, where anesthesiologists are in short supply.

This article explores whether the change in CMS policy toward anesthesia supervision had a negative impact on patient outcomes. We begin by examining the absolute level and time trends of adverse patient outcomes within the states that opted out and those that did not.

It is important to note, however, that differences in these gross measures do not constitute prima facie evidence of a response to the policy change. The act of opting out of the supervision requirement does not necessarily imply any changes in the actual practice of anesthesia within any hospital in a state. The opt-out exemption does not mandate that hospitals allow certified registered nurse anesthetists to provide anesthesia without supervision by a surgeon or an anesthesiologist. It means only that Medicare would not require such supervision as a condition of reimbursement.

Nonetheless, if patient outcomes are unchanged after a state has opted out, as we show to be the case, then the requirement that governors petition CMS to exempt certified registered nurse anesthetists from physician supervision is unnecessary and should be rescinded.

Study Data And Methods

For the opt-out policy to affect outcomes, two conditions must be fulfilled. First, the opt-out policy must result in a shift in anesthesia arrangements. If the policy change does not affect anesthesia arrangements, then it alone could not affect patient outcomes.

Second, there must be some systematic difference in the outcomes associated with the different anesthetist arrangements. If the outcomes across the different arrangements are the same, then even if the policy change affected anesthesia arrangements, it would not affect overall patient outcomes in opt-out states.

We therefore examined whether there was a material change in the provision of anesthesia services away from anesthesiologists in favor of certified registered nurse anesthetists and, separately, whether there is evidence of different

outcomes associated with the two types of anesthetists. In examining outcomes, we first determined whether case-mix complexity differed between opt-out and non-opt-out states and by anesthetist training.

Data Source To address the research questions, we used the 5 percent Medicare Inpatient (Part A) and Carrier (Part B) Medicare limited data set files for 1999–2005. The files include all Part A claims from facilities and Part B claims from physicians and suppliers for a 5 percent sample of beneficiaries.

Given the distribution of states opting out of physician supervision at different times, we used seven calendar years of Medicare 5 percent data. This gives three full years of post-opt-out data for six of fourteen opt-out states and at least two full years of data for eleven opt-out states. Any deleterious effects of shifts to more anesthesia by unsupervised nurse anesthetists should be seen soon after a state opts out because more anesthesia complications would occur during the patient's inpatient hospital stay.

We abstracted Part A claims for each study year for all admissions in all Medicare surgical diagnosis-related groups (DRGs), which were 98,000–114,000 claims per year. Procedures taking place in ambulatory surgery centers were excluded because of uncertainty in measuring mortality or complications in those cases.

Because the 5 percent limited data sets do not contain the patient's measurement on the physical status scale of the American Society of Anesthesiologists, we merged onto the claims the anesthesia base units for the most complex anesthesia procedure (*International Classification of Diseases*, Ninth Revision, or ICD-9) code for each admission. For example, the base unit for a thyroid biopsy is 3; for cardiac catheterization, 8; and for tracheobronchial reconstruction, 18.¹⁴

We used the two Part B procedure modifier fields to identify three anesthesia provider arrangements: anesthesiologists practicing solo, certified registered nurse anesthetists practicing solo, and team anesthesia in which anesthesiologists supervise or direct nurse anesthetists. If a modifier on either a nurse anesthetist or an anesthesiologist claim indicated supervision or direction of the nurse anesthetist, then the anesthesia category was defined as team anesthesia.

Any nonteam hospitalization with a certified registered nurse anesthetist claim but no anesthesiologist claim was coded as certified registered nurse anesthetist solo. Finally, any procedure with an anesthesiologist claim not already characterized as team or certified registered nurse anesthetist solo was considered anesthesiologist solo.

Because all date fields in the data are aggregated

gated to the quarter level, it was not possible to accurately link inpatient Part B anesthesia claims to specific hospitalizations for patients who had multiple hospitalizations in the same quarter. Therefore, we excluded patients with more than one hospitalization in a quarter.

The resulting seven-year pooled file contained 741,518 surgical discharges. Roughly one-third did not have any anesthetist claim. The majority of cases without anesthesia bills were for procedures that often do not require an anesthetist, such as percutaneous transluminal coronary angioplasty, pacemaker lead inserts, sigmoidoscopies, bronchoscopies, diagnostic catheterizations, and endoscopic surgeries.

Hospitalizations without a Part B anesthesia claim were excluded unless a surgical procedure took place in a Medicare “pass-through” hospital. In these hospitals, claims for services by nurse anesthetists are rolled into (“passed through”) the Part A hospital claims. Therefore, observations from these hospitals were assigned to the certified registered nurse anesthetist solo category.

Hospitalization claims were also deleted if a Part B inpatient anesthetist claim was present in the previous quarter for the same beneficiary with no admission claim in that quarter. We assumed in those cases that the anesthetist filed his or her claim earlier than the hospital’s claim for the same admission.

This left us with 481,440 hospitalizations for analysis, of which 412,696 were in non-opt-out states and 68,744 were in opt-out states. Of the latter, 41,868 hospitalizations occurred before the state had opted out.

Analytic Methods We analyzed two outcomes measures: inpatient mortality and complications. Mortality is reported on the Medicare discharge abstract. To measure possible anesthesia complications, we identified seven relevant patient safety indicators developed by the Agency for Healthcare Research and Quality:¹⁵ complications of anesthesia (patient safety indicator 1); death in low-mortality diagnoses (indicator 2); failure to rescue from a complication of an underlying illness or medical care (indicator 4); iatrogenic pneumothorax, or collapsed lung (indicator 6); postoperative physiologic and metabolic derangements, or physical or chemical imbalances in the body (indicator 10); postoperative respiratory failure (indicator 11); and transfusion reaction (indicator 16). (Descriptions of each complication are provided in the online Appendix.)¹⁶

Each of these complications occurred only infrequently. Therefore, we used a single no/yes indicator (0 for no, 1 for yes) to show if any one of them occurred on a single admission.

State-level analyses cannot completely answer the question of whether allowing certified registered nurse anesthetists to provide anesthesia without supervision exposes patients to meaningful additional risks. By focusing on individual hospitalizations, however, it is possible to use Medicare claims to isolate any impact of opting out by anesthesia provider type.

It is possible that hospital managers systematically refer more difficult procedures to anesthesiologists and less difficult ones to nurse anesthetists. We therefore controlled for patient characteristics and procedure complexity.

We compared inpatient mortality rates between opt-out and non-opt-out states, stratifying by year and anesthesia arrangement. Anesthesiologists practicing alone were involved in more complex surgical procedures than certified registered nurse anesthetists practicing alone.

Therefore, we adjusted anesthesiologist solo mortality rates by applying to the anesthesiologist solo group the nurse anesthetist case-mix for surgeries that the two providers had in common.

Frequency weighting was done at the diagnosis-related group level for each state, separately. T-tests were used to measure the differences in the adjusted mortality rates between opt-out and non-opt-out states within each stratum.

We also estimated logistic regressions using indicators for state opt-out status before and after opt-out and for anesthesia provider, to determine the effects of these variables on the probability of mortality and complications. Also included were the patient’s age, sex, and race, along with year indicators and the procedure’s anesthesia base units, to measure its complexity. The model was applied to surgical admissions pooled across all seven years in all opt-out and non-opt-out states.

Results

Who Provides Anesthesia We examined whether a state’s decision to opt out of the supervision requirement resulted in different anesthesia arrangements. In our sample, the certified registered nurse anesthetist solo group provided anesthesia in 21 percent of surgeries in opt-out states and about 10 percent in non-opt-out states (Exhibit 1). Solo provision of anesthesia by nurse anesthetists increased over time in opt-out and non-opt-out states.

Although the absolute increase was roughly five percentage points in both opt-out and non-opt-out states, the proportional increase was larger in non-opt-out states (71 percent) than in opt-out states (28 percent). The growth of the solo share by certified registered nurse anesthetists in opt-out states came at the expense of

Percentages Of Surgical Anesthetics By Anesthesia Provider, In States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	17.6	40.7	41.7	7.0	47.3	45.8
2000	18.4	42.5	39.1	8.3	46.7	45.0
2001	20.2	42.0	37.8	9.2	45.3	45.5
2002	22.2	41.7	36.1	9.9	44.7	45.4
2003	22.9	42.5	34.7	10.3	43.7	46.0
2004	23.4	42.0	34.6	11.3	42.3	46.5
2005	22.5	42.8	34.7	12.0	41.5	46.5
1999–2005	21.0	42.0	37.0	9.7	44.5	45.8

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. NOTES Not all totals equal 100 percent because of rounding. CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together.

team anesthesia, while in the non-opt-out states it came at the expense of anesthesiologist solo anesthesia.

Differences By Patient Type Or Procedure Before comparing trends in outcomes, we examined whether the case-mix of certified registered nurse anesthetists and anesthesiologists differed by type of patient or procedure. Exhibit 2 shows patient characteristics as of 2005, stratified by anesthesia provider and state opt-out status. The figures have not been adjusted for the different diagnosis-related groupsurgical cases that are typical of the two types of anesthesia providers. With the exception of base units, the differences in patient characteristics between the certified registered nurse anesthetist solo and anesthesiologist solo groups, although statistically significant, were clinically minor and would not explain large differences in patient outcomes within opt-out and non-opt-out states.

With the exception of the prevalence of African American patients, the differences within provider groups across opt-out status were also

minimal.

In opt-out and non-opt-out states, the mean number of base units in the anesthesiologist solo group was about a full point higher than in the certified registered nurse anesthetist solo group ($p < 0.05$, or unlikely to be due to chance). This indicates that solo anesthesiologists were performing more complex or difficult procedures than the nurse anesthetist solo group. One might have expected higher relative complexity by nurse anesthetists practicing solo in opt-out states, given their higher proportion of cases.

However, many opt-out states are rural, and surgery and anesthesia in those states may be less complex overall than in more urban states. This is because patients with more difficult surgical procedures are referred to major urban hospitals with experienced surgical teams and technologies.

Outcomes For Patients Given that the solo practice of nurse anesthetists did increase in opt-out states, we next determined whether there were any differences in patient outcomes by

Characteristics Of Anesthesia Patients In States That Did And Did Not Opt Out Of Physician Supervision, 2005

Characteristic	Opt-out states			Non-opt-out states		
	CRNA solo (n = 2,310)	MDA solo (n = 4,605)	Team (n = 3,736)	CRNA solo (n = 7,554)	MDA solo (n = 26,354)	Team (n = 29,511)
Age 75+	51%	48%	45%	44%	47%	44%
Male	41%	45%	44%	43%	45%	44%
African American	1%	2%	2%	8%	7%	11%
Base units ^a	7.2	8.3	7.6	7.2	8.4	7.6

SOURCE Authors' analysis of Medicare Parts A and B claims, 2005 limited data set. NOTES CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. All comparisons of CRNA solo with MDA solo are significant at the 95 percent confidence level. ^aBase units indicate the severity of the case; see text.

anesthesia arrangement. We started with mortality rates within each hospital for procedures that the two provider types had in common in opt-out and non-opt-out states.

In non-opt-out states, mortality rates for the three anesthesia arrangements followed a general downward trend throughout the seven-year period, from 3.1–3.5 percent to 2.2–2.8 percent (Exhibit 3). A general downward trend is also apparent in opt-out states. Of particular interest is the mortality trend for the certified registered nurse anesthetist solo group in opt-out states. The rate increased from 1999 to 2001—prior to the introduction of the opt-out provision—and decreased from 2001 to 2005. December 2001 was when the first state, Iowa, opted out of the supervision requirement.

Multivariate Analyses Exhibit 4 shows the results of the multivariate analyses for inpatient mortality and complications. It presents the odds ratios for each of the three provider groups in three different opt-out status conditions: non-opt-out states, opt-out states prior to opting out, and opt-out states after opting out. In addition to the provider group and opt-out status indicators, the model controlled for patients' age categories, sex, and race; anesthesia procedure base units; indicators for the ten highest-mortality diagnosis-related groups; and an annual time trend.

The reference group for the odds ratios for both mortality and complications was the anesthesiologist solo group in non-opt-out states. All eight comparison cells for mortality had odds ratios less than 1.0, which indicates that mortality occurred with lower probability in all other combinations of provider and opt-out status than it did with solo anesthesiologists in non-opt-out states (the differences are all significant at the 0.05 level). In opt-out states, there were no

statistically significant mortality differences between the periods before and after opting out.

Unlike mortality, complication rates did not differ between anesthesiologist and certified registered nurse anesthetist solo groups in non-opt-out states (Exhibit 4).¹⁷ Yet, as with mortality, nurse anesthetists practicing solo in opt-out states had a lower incidence of complications (odds ratios were 0.798 before opting out and 0.813 after) relative to solo anesthesiologists in non-opt-out states. These differences were statistically significant for both time periods.

In opt-out states, complication rates for the nurse anesthetist solo group were essentially identical to those for the anesthesiologist solo group. The difference between complication rates for nurse anesthetist solo and team anesthesia was also not statistically different in opt-out states.

Discussion

Linking the change in CMS reimbursement policy to changes in patient outcomes requires both that the proportion of surgical procedures for which certified registered nurse anesthetists alone provided anesthesia changed as a consequence of the policy change, and that the type of anesthesia provider affects the likelihood of in-hospital mortality or other adverse event. Our analysis does not support either of the two.

Instead, we found that from 1999 to 2005, the proportion of surgeries in which anesthesia was provided by nurse anesthetists with no anesthesiologist involvement increased by five percentage points in both opt-out and non-opt-out states. However, the rate of increase was nearly three times as great in non-opt-out states as in opt-out states because nurse anesthetist solo rates initially were lower in the former than in



Surgical Inpatient Mortality Rates (Per 100 Patients) By Anesthetist Arrangement, In States That Did And Did Not Opt Out Of Physician Supervision, 1999–2005

Year	Opt-out states			Non-opt-out states		
	CRNA solo	MDA solo	Team	CRNA solo	MDA solo	Team
1999	1.76	3.45	2.92	3.10	3.50	3.19
2000	2.50	3.67	1.79	3.16	3.21	2.58
2001	3.01	2.80	1.94	3.54	3.68	3.19
2002	2.26	2.72	2.15	3.09	3.44	2.95
2003	2.49	2.39	2.01	3.21	3.58	2.86
2004	1.86	3.82	2.03	2.84	3.20	3.08
2005	2.03	1.32	1.45	2.34	2.76	2.20

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. NOTES CRNA solo is certified registered nurse anesthetist without anesthesiologist. MDA solo is anesthesiologist without CRNA. Team is anesthesiologist and CRNA working together. MDA solo and team mortality rates are based on CRNA case-mix. Inpatient mortality is attributable to anesthesia and all other causes.

Likelihood Of Death And Complications From Anesthesia, For Different Combinations Of Anesthesia Provider Groups And States' Opt-Out Status: Odds Ratios

Anesthesia provider	Mortality			Complications		
	Non-opt-out states	Opt-out states		Non-opt-out states	Opt-out states	
		Before opting out	After opting out		Before opting out	After opting out
MDA solo	1.00	0.797 ^a	0.788 ^a	1.00	0.824 ^a	0.818 ^a
CRNA solo	0.899 ^a	0.651 ^a	0.689 ^a	0.992	0.798 ^a	0.813 ^a
Team	0.959 ^a	0.708 ^a	0.565 ^a	1.067 ^a	0.927	0.903

SOURCE Medicare Parts A and B claims, 1999–2005 limited data sets. NOTES MDA solo is anesthesiologist without certified registered nurse anesthetist (CRNAs). CRNA solo is CRNA without anesthesiologist. Team is anesthesiologist and CRNA working together. The model includes year, base units, diagnosis-related groups, and the patient's age, race, sex. Complications include patient safety indicators 1, 2, 4, 6, 10, 11, and 16 of the Agency for Healthcare Research and Quality; see text. ^aOdds ratio is significantly different from 1 for MDA solo ($p < 0.05$).

the latter. This implies that the increase in the certified registered nurse anesthetist solo share in opt-out states cannot be ascribed wholly, if at all, to the change in the CMS supervision policy.

Whatever forces are driving the growing share of nurse anesthetist solo cases, they appear to be different in the fourteen opt-out states than in the non-opt-out states. In opt-out states, the seven-percentage-point decline in team anesthesia resulted in more solo practice by both types of anesthetists. Anesthesiologists practicing solo explained about one-third of the decline in team anesthesia, and nurse anesthetists practicing solo accounted for the other two-thirds. Elsewhere in the country, team anesthesia rates were constant.

Despite the shift to more anesthetics performed by nurse anesthetists, no increase in adverse outcomes was found in either opt-out or non-opt-out states. In fact, declining mortality was the norm. Moreover, the mortality rate for the nurse anesthetist solo group was lower than for the anesthesiologist solo group in opt-out states both before and after opting out, although the difference was statistically significant only before the state opted out.

These results do not support the hypothesis that allowing states to opt out of the supervision requirement resulted in increased surgical risks to patients. Nor do the results support the claim that patients will be exposed to increased risk as a consequence of more nurse anesthetists' practicing without physician supervision.

We did find that case-mix complexity was different for the two types of providers. Anesthesia base units for procedures in which anesthesiologists practiced solo were a full point higher than for procedures in which certified registered nurse anesthetists worked alone.

Although base units might not completely de-

scribe the complexity of either surgical or anesthetic procedures, base units were associated with a statistically greater mortality risk in our multivariate model. We estimate that each one-point increase in procedure base units is associated with a 7 percent higher mortality risk.

To this extent, base units can capture a sizable part of the complexity and risk of the procedures. Moreover, we believe that using additional measures of complexity would not qualitatively change our results.

There were clearly differences between the opt-out and non-opt-out states that were not a consequence of their opt-out status. With the exception of the proportion of African American patients, it does not appear that these differences were primarily caused by patient characteristics such as sex and age.

Yet opt-out states had lower mortality and complication rates than non-opt-out states, even prior to opting out. This suggests that some unobserved difference existed between opt-out and non-opt-out states, perhaps related to the fact that opt-out states were more rural and tended to be located in the West and Midwest.

In any case, the policy conclusions supported by this study remain valid. In opt-out states, mortality and complication rates for the certified registered nurse anesthetist solo group did not vary greatly between the period before opting out and the period after. That means that our data do not support the hypothesis that patients are exposed to increased surgical risk if nurse anesthetists work without physician supervision.

Policy Recommendations

Our analysis of seven years of Medicare inpatient anesthesia claims suggests that the change in CMS policy allowing states to opt out of the

physician supervision requirement for certified registered nurse anesthetist reimbursement was not associated with increased risks to patients. In particular, the absolute increase in the provision of anesthesia by unsupervised nurse anesthetists in opt-out states was virtually identical to the increase in non-opt-out states, and the proportional increase was smaller in opt-out states.

This lends no support to the belief that a meaningful shift in provider shares occurred as a consequence of the policy change. Similarly, our analysis found no evidence to suggest that there is an increase in patient risk associated with anesthesia provided by unsupervised certified registered nurse anesthetists.

Both a change in the proportion of anesthesia provided by the different groups—nurse anesthetists alone, anesthesiologists alone, and

nurse anesthetists and anesthesiologists working in teams—and a difference in the outcomes of the different groups are necessary to conclude that the change in CMS policy led to changes in patient safety. Because our data provide no evidence to support either of these conditions, we conclude that patient safety was not compromised by the opt-out policy.

We recommend that CMS return to its original intention of allowing nurse anesthetists to work independently of surgeon or anesthesiologist supervision without requiring state governments to formally petition for an exemption. This would free surgeons from the legal responsibility for anesthesia services provided by other professionals. It would also lead to more-cost-effective care as the solo practice of certified registered nurse anesthetists increases. ■

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NOTES

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