DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, and 485

[HCFA–3049–F]

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Medicare and Medicaid Programs; Hospital Conditions of Participation: Anesthesia Services.

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Anesthesia Services Condition of Participation (CoP) for hospitals, the Surgical Services Condition of Participation for Critical Access Hospitals (CAH), and the Ambulatory Surgical Center (ASC) Conditions of Coverage Surgical Services. This final rule changes the physician supervision requirement for certified registered nurse anesthetists furnishing anesthesia services in hospitals, CAHs, and ASCs. 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. States and hospitals are free to establish additional standards for professional practice and oversight as they deem necessary.

The hospital anesthesia services CoP, CAH surgical services CoP, and the conforming change to the anesthesia Conditions of Coverage apply to all Medicare and Medicaid participating hospitals, CAHs, and ASCs.

EFFECTIVE DATE: These regulations are effective on March 19, 2001.

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I. Background

A. Legislation

Sections 1861(e)(1) through (e)(8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Section 1820 of the Act contains criteria for application for States establishing a Critical Access Hospital. Sections 1832(a)(2)(F)(i) and 1833(i) provide coverage requirements for ASCs. Section 1861(bb) of the Act, provides definitions for certified registered nurse anesthetists (CRNAs) and their services.

B. General

On December 19, 1997, we published the proposed rule, ''Hospital Conditions of Participation, Provider Agreements and Supplier Approval,'' (62 FR 66726) in the **Federal Register**. This proposed rule generated over 60,000 public comments and approximately one-third of these comments addressed the proposed condition eliminating the Federal requirement for physician supervision of a licensed independent practitioner permitted by the State to administer anesthetics.

In 1997, when we proposed our changes to the current hospital conditions of participation (CoPs), we stated our desire to move toward standards that are patient-centered, evidence-based, and outcome oriented. We also stated that a fundamental principle was to facilitate flexibility in how a hospital meets our performance expectations, and eliminate structure and process requirements unless there is evidence that they are predictive of desired outcomes for patients. Where there is agreement on a structure or process requirement predictive of desired patient outcomes, we included that in our proposed rule. In fact, comments on the standard for physician supervision of CRNAs reflect a split between those who support flexibility in allowing States and hospitals to make decisions about anesthesia services and those who oppose the provision, supporting, instead, the structural requirement for physician supervision. We have already finalized the Organ Donation and Transplantation and Patients' Rights conditions, which were contained in the December 19, 1997 proposed hospital rule. We are now finalizing part of the anesthesia services standard describing anesthesia administration. We continue to work to finalize the other issues in the December 19, 1997 hospital conditions of participation proposed rule.

C. Need for Amended Anesthesia Services CoP

The existing hospital CoPs require hospitals, CAHs, and ASCs to provide quality care by adhering to our organizational and staffing requirements. The current hospital CoPs are not written in a way that promote or encourage a hospital, CAH, or ASC to assess the quality of care and improve patient outcomes. One of the clear messages we received from industry groups and professionals as we pursued this change in regulatory approach is that the old way of focusing on structure and process no longer represented current practice or the best available method to foster delivery of quality health care services.

Since publication of the December 19, 1997 proposed rule, we have continued to receive input from representatives of individual industry groups and have analyzed thousands of public comments from individual providers, beneficiaries, hospitals, and professional and provider organizations. We have given careful consideration to the scientific literature cited by commenters. We have found no compelling scientific evidence that an across-the-board Federal physician supervision requirement for CRNAs leads to better outcomes, or that there will be adverse outcomes by relying on State licensure laws instead.

We are also responding to considerable Congressional activity that has occurred since the 1997 publication of the proposed rule. Interest by Congress on both sides of the issue of physician supervision resulted in Appropriations Conference committee language in the Conference Report to the Balanced Budget Refinement Act (BBRA) of 1999 (H. Conf. Rep. No.106–

479, at 873 (November 18, 1999)) urging the Secretary to determine whether there was sufficient information to move forward with a final rule. The literature we reviewed (see appendix) indicated that the anesthesia-related death rate is extremely low, and that the administration of anesthesia in the United States is safe relative to surgical risk.

There have been no studies published within the last 10 years demonstrating any need for Federal intervention in State professional practice laws governing CRNA practice. Currently, there is no reason to require a Federal rule in these conditions of participation mandating that physicians supervise the practice of another State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that health professional. We believe there is no reason to change our proposed approach, which gives States and hospitals the flexibility to determine necessary oversight. We believe the change, based on the available information, appropriately reflects the important value of regulatory flexibility.

D. Recognizing State Laws and Professional Scope of Practice

Congress has specified which non-physician health professionals may receive separate payment for their professional services (such as CRNAs and nurse practitioners). In addition, Congress left the function of licensing these health professionals to the States. Medicare recognizes the scope of practice established by the States for these health professionals. Prior to this final rule, Medicare's hospital CoPs did not have Federal requirements for physicians to supervise the practice of another State-licensed health professional where there is a statutory provision authorizing direct Medicare payment for the services of that health professional, with the sole exception of the Federal requirement for physician supervision of CRNAs. We do not believe that there is evidence to support maintaining a special Federal requirement for physician supervision of CRNAs.

Eliminating the Federal requirement for physician supervision of CRNAs is not a judgment on our part that one health professional is better than another or that one type of care is superior. The change in regulatory approach reflected in this final rule was discussed in the preamble of the hospital CoPs proposed rule (62 FR 66740). This rule establishes a shared commitment to quality care among us, the States, and Medicare providers. Medicare providers are in the best position to assess the evidence and consider data relevant to their own situations (for example, physician access, hospital and patient characteristics and needs of rural areas) about the best way to deliver anesthesia care. Hospitals can always exercise stricter standards than required by State law. We will monitor the effects on the quality of anesthesia care furnished to Medicare beneficiaries resulting from the greater flexibility provided to States and hospitals under this rule.

II. Analysis of and Responses to Public Comments

We received approximately 20,000 comments on the issue of physician supervision of CRNA administration of anesthesia. Comments were largely split among CRNAs, representatives of rural areas, and supporters of State oversight who favor the proposal; and physicians who, in general, opposed the proposal and argued that anesthesia administration is the practice of medicine, requiring advanced medical education. A summary of the major issues and our responses follow:

State Law and Professional Scopes of Practice

Comment: The majority of comments focused on whether States' scope-of-practice laws are the proper level of regulatory oversight. Most physicians maintained that anesthesia is the practice of medicine which should only be practiced by a licensed physician, and opposed the provision permitting State licensed independent practitioners to administer anesthetics without physician supervision. These commenters argued that, because of disparities among the various States, laws are inconsistent and result in inequality of care across the country. As a result, they stated that Medicare beneficiaries would lose an important Federal guarantee for minimum standards of anesthesia care, and instead would be subjected to a variety of State laws. Conversely, other commenters argued that the Federal rule preempts State law, creating barriers to practice and limiting opportunity for nurse anesthetists licensed as independent practitioners. A physician supervision requirement, they asserted, diminishes the role of local jurisdictions and authorities that regulate and/or license other health professions and aspects of health service delivery. Commenters also stated that the current Federal requirement for physician supervision has been a disincentive for employers to hire CRNAs, decreasing flexibility and efficiency in anesthesia services, and limiting access in certain areas. One commenter wrote that it is the State that best understands its individual geographical, population, and financial needs and resources and how these resources can best be utilized to deliver safe, quality anesthesia services.

Response: We respect the authority of States to meet regional/local needs. Setting forth a final rule that allows States the ultimate determination regarding which licensed independent practitioners may administer anesthesia does not prohibit any State or hospital from requiring physician supervision. It will effectively provide greater discretion to State authorities that are experienced at regulating the licensing, education, training, and skills of the professionals practicing under their purview, without the burden associated with duplicative regulatory oversight. There is no evidence that States are less concerned with ensuring safety and quality than the Federal government, especially where the health of their citizens is at stake. We disagree that States are less capable or less committed to protecting patients and ensuring quality anesthesia services than the Federal government. The final rule removes the ''across the board'' Federal requirement for physician supervision in every case of anesthesia administration. At the same time, it broadens overall flexibility by permitting individuals and authorities closer to patient care delivery to make decisions about the best way to deliver health care services.

Comment: Some commenters were concerned that this change in regulatory approach would grant the right to practice medicine to individuals who were not properly prepared to do so. One commenter pointed out that we were giving unsupervised privileges to prescribe narcotics, paralytic agents, and cardiac drugs to people who have neither a medical license nor the training and credentialing that is associated with a medical license.

Response: States regulate professionals who may prescribe medicines as well as which medical procedures may be performed under a professional license through their professional practice laws. Our regulations do not determine prescribing authority or grant medical licenses, and this final rule does not change the traditional purview under which these professional scope-of-practice issues have occurred in the past. The final rule does not prohibit physicians from practicing medicine, nor does it allow nurse anesthetists to practice beyond the scope of their

practice or authority granted them by States.

Comment: We received several comments from both physicians and nurse anesthetists in support of allowing physicians, hospitals, and surgical centers more responsibility for the care they furnished. Some commenters noted that the medical staffs within institutions should determine guidelines for supervision of all health care personnel contributing to the medical care of patients. Several commenters recognized the value of allowing hospital boards and medical staffs to set the standards of care. These commenters thought that relying on greater accountability from doctors and hospitals instead of Federal regulation would lead to better care for patients. Commenters noted that this rule would allow hospitals to set standards different from us, based on review and input from physicians and other health professionals. The American Hospital Association (AHA) also supported this rule change, stating ''This new policy ensures that only personnel trained in administering anesthesia are allowed to do so. This requirement balances accountability with flexibility.''

Response: We agree that providers have a shared responsibility, with us and the States, to assure quality standards of practice. We are pleased that the hospital industry recognizes the values of accountability and flexibility in Federal regulation. Allowing States to make determinations about health care professional standards of practice, and hospitals to make decisions regarding the delivery of care, assures that those closest to, and who know the most about, the health care delivery system are accountable for the outcomes of that care.

Comment: Several commenters stated that the administration of anesthesia has never been exclusively the practice of medicine. These commenters noted that anesthesia administration is within the scope of practice of nurses, physicians, dentists, podiatrists, and other professionals who have been properly educated and credentialed in the field of anesthesia. Since more surgical procedures are moving out of the hospital into clinic and office settings, an institution needs the flexibility to utilize the anesthesia professional of its choice which best matches the needs of the patient.

Response: Although this final rule governs anesthesia administration in hospital, CAH, and ASC settings only, we agree with the need for flexibility in other settings, especially as surgical techniques, methods for administering anesthesia and the availability of drugs is improved.

We believe that the range of patient types, surgical procedures, new technologies, and provider settings (for example, hospital outpatient departments, intensive care units, and teaching hospitals) makes an across-the-board Federal requirement overly burdensome. Differences between a healthy young patient undergoing minor surgery in a hospital outpatient department and a medically compromised, elderly patient undergoing major surgery in a large teaching facility are so great that a single Federal requirement is not applicable in every situation.

Comment: Several commenters objected to our arguments that eliminating CRNA supervision would, ''allow greater flexibility to hospitals and practitioners'' and would ''give deference to State scope-of-practice laws''. These commenters believe that our reasoning is weak, especially in the absence of documentation that either of these issues is a problem.

Response: We disagree with these commenters. As previously noted, we respect State control and oversight of health care professionals by deference to State licensing laws which regulate professional practice. There is no reason to consider physician supervision of CRNAs a special case requiring a national standard. Advances in anesthesia and surgical techniques, the availability and discovery of new drugs, and the varying medical presentations of patients make it less prudent to rely on a single national standard requiring physician supervision of CRNAs to be applied in every situation. Doing so risks losing the accountability of practitioners, both to make clinical decisions based on the needs of patients, and to utilize resources effectively. We believe States need flexibility from Federal oversight of those processes, such as professional licensing, for which they are ultimately accountable. In fact, it is at the State level where much direct input by health professionals into scope-of-practice and licensing laws takes place.

Comment: One commenter asked what rule would be operative in the absence of any State law.

Response: The final rule allows only a licensed practitioner permitted by the State to administer anesthetics to do so. Therefore, State health professional practice laws, such as those covering nurse and physician practice, as well as hospital licensing requirements, would be the basis for determining which health care professionals can administer anesthesia in any given State.

Safety and Quality of Care

Comment: Many of the commenters who wrote expressing concern over quality of anesthesia services referred to published research to support their point of view. For example, many commenters who support the proposed rule stated that evidence shows anesthesia administered by CRNAs to be as safe as that administered by anesthesiologists. In contrast, we also received comments from anesthesiologists who noted positive patient outcomes from anesthesia administration to be related to the presence of the anesthesiologist. The articles most frequently cited by commenters were three by Jeffrey Silber, M.D. and colleagues (1992, 1995, 1997), and another by J.P. Abenstein and M.A. Warner (1996). Many commenters claimed these studies concluded either an anesthesiologist alone, or a CRNA in ''collaboration'' with an anesthesiologist, had better patient outcomes than a CRNA alone. Many commenters contend, erroneously, the recommendations from the Abenstein & Warner article were adopted by the Minnesota legislature (although it is not clear to what recommendations the commenters were referring). Many other commenters urged us not to consider the change made by this rule until there is solid, scientifically defensible outcome data to establish that independent nurse anesthesia care is just as safe as anesthesiologist care.

Response: The conclusions of the commenters were not supported by findings from the studies they cited, nor do the studies conclude that States provide inadequate oversight and that a Federal standard is therefore necessary. We reviewed available literature and found the following major conclusions (see appendix).

- All literature surveyed agreed that the anesthesia-related death rate is extremely low, and the administration of anesthesia in the United States is safe relative to surgical risk. In fact, according to the 1999 Institute of Medicine Report *To Err Is Human,* ''anesthesia mortality rates are about one death per 200,000–300,000 anesthetics administered, compared with two deaths per 10,000 anesthetics administered in the early 1980s,'' a 40- to 60-fold improvement.
- There are no studies published within the last 10 years that are specific to the issue of the final rule, namely provision of anesthesia care by CRNAs practicing without physician supervision. All of the studies we reviewed had significant limitations. Conclusions are limited by these

studies' failure to control adequately for possible correlations among variables such as higher risk patients and hospital characteristics (for example, size and sophistication of medical technology) as they would affect deaths attributable to anesthesia.

• There is no evidence that there would be adverse outcomes by relying on States and hospitals to regulate the appropriate supervision and scope of practice of health professionals administering anesthesia. Nor has there been any evidence that States do a poor job in regulating and overseeing health care professional practice or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

In the Silber studies, the authors did not conclude that CRNAs may be providing poor care that might more likely lead to negative outcomes. The 1992 study did not address whether there is an association between patient outcomes and the type of professional who furnished anesthesia. The anesthesia variable used in the study was not specific to the patient, rather it was a variable at the hospital level (for example, percent of anesthesiologists who are board-certified). The anesthesia variable might be a proxy indicator of quality of the hospital: Thus, there would be lower mortality in the higher quality hospitals and if a complication occurred the patient would more likely be rescued.

Silber urges ''that the limitations of the project be recognized.'' The limitations include: There were relatively few deaths, adverse outcomes and failures, and relatively few patients per hospital so the rates could only be compared for groups of hospitals, not specific facilities.

In a subsequent article to the one summarized above, Silber and colleagues (1995) found that ''most of the predictable variation in outcome rates among hospitals appears to be predicted by differing patient characteristics rather than by differing hospital characteristics, that is, by who is treated rather than by the resources available for treatment.'' The authors found higher proportions of board-certified anesthesiologists to be associated with lower death and failure rates, but also with higher adverse occurrence rates. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. The study did not address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another. Silber and his colleagues (1997) have also conducted methodological studies that compare the usefulness of three outcome measures, mortality, complication and failure-to-rescue rates. They concluded that for the general surgical procedures studied, the complication rate is poorly correlated with the death and failure rate. The authors suggest that great caution be taken when using complication rates and that they should not be used in isolation when assessing hospital quality of care. The study did not address the relationship between the patient outcomes and the type of professional who furnished the anesthesia care. Nor did the study address the issue of provision of anesthesia care by CRNAs supervised and not supervised by physicians, the issue in the rule. The article presents no information that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

We have also reviewed a more recently published article by Dr. Silber (July 2000) and colleagues from the University of Pennsylvania. This article also is not relevant to the policy determination at hand because it did not study CRNA practice with and without physician supervision, again the issue of this rule. Moreover, it does not present evidence of any inadequacy of State oversight of health professional practice laws, and does not provide sound and compelling evidence to maintain the current Federal preemption of State law.

Even on its own terms, the study has the following methodological shortcomings:

• The study used a non-experimental research design and only examined claims data, instead of reviewing medical records or observing actual care. Even though the researchers statistically controlled for 106 proxy indicators of care, without a stronger research design, they can only make a weak conclusion about an ''association'' between a variable and an outcome.

• The study did not control for the cause of death. Cases where a patient died from an anesthesia related cause, the surgery itself, an unrelated medical error, or an unknown medical condition are all considered, regardless of the cause of death. Not having data on deaths actually attributed to anesthesia is problematic since the mortality data used covers any death occurring within 30 days of a hospital admission. Events occurring 30 days from admission cannot be attributed to the anesthesia care alone. While the researchers argue that ''delayed'' death (that is, within 30 days of admission) is the appropriate measure of mortality for anesthesia care, the study does not produce causal evidence for such a theory. At a minimum, the researchers could have presented results for mortality measured for shorter periods of time such as within 72 hours of admission which may or may not have shown different outcomes for short-term and delayed deaths.

• Both the study and comparison groups included cases where physicians supervised CRNAs and personally furnished anesthesia. (The study group also included cases where anesthesiologists medically directed residents). The purpose of the study was to examine differences when an anesthesiologist versus a non-anesthesiologist physician is involved in the case. One cannot use this analysis to make conclusions about CRNA performance with or without physician supervision.

• The study used data where anesthesia was furnished by unknown suppliers (incorrectly referred to in the article as ''unknown providers'') either personally providing care or supervising CRNAs. Because a supplier is not a physician there are likely to be data coding errors which could contaminate and bias the results.

Even if the methodological shortcomings were fixed, because the study did not address the issue in the final rule, it is inappropriate to impute results from this study to the issue in this final rule, the provision of care by CRNAs supervised and not supervised by physicians.

Even if the recent Silber study did not have methodological problems, we disagree with its apparent policy conclusion that an anesthesiologist should be involved in every case, either personally performing anesthesia or providing medical direction of CRNAs. Such a policy is much more restrictive than current Medicare policy because it would prohibit non-anesthesiologist physicians to supervise CRNAs. This would make it difficult to perform surgeries in many small and rural hospitals because anesthesiologists generally do not practice in these hospitals.

Finally, even if we were to consider that the Silber article should guide our policy, we note, that due to the difference between relative risk and absolute risk, the reported size-effect is too small to cause us to change our

decision. The Silber article reported an odds ratio for death of 1.08 corresponding to 2.5 excess deaths per 1000 cases (relative risk). However, due to the lack of medical record review in this study these excess deaths cannot be solely attributed to anesthesia care and thus is not the absolute risk. For example, if we accept the IOM review of the literature of 33.3–50 anesthesia related deaths per 10 million (*i.e.,* one per 200,000–300,000) then the absolute risk of excess deaths would be in the range of 2.7–4.0 per 10 million (.08 times range of 33.3–50). This size of absolute risk must be balanced against the risk of death due to lack of timely access to anesthesia services because of a federal imposition of a supervision requirement. At a minimum States are certainly capable of balancing the risks of lack of supervision versus the shortage of anesthesiologists given the supply of anesthesiologists in each of their respective States.

The Abenstein & Warner (1996) paper describes a number of aspects of anesthesia care and reviews studies in several areas. The paper notes that there has been a dramatic improvement in anesthetic deaths in the last 15 years: ''Since 1979, five studies have documented a remarkably abrupt decrease in anesthetic-related death rates, morbidity, and risk of perioperative deaths.'' The paper concludes that: For many patients, it is now as safe to be anesthetized as to be a passenger in an automobile.''

The paper notes that ''identifying the cause for the improvement in anesthetic outcome is as problematic as determining the cause of perioperative death.'' The paper indicates that ''huge numbers of surgical patients (that is, >1,000,000) must be enrolled in studies to provide the statistical power needed to determine whether there are associations between perioperative disability or death and various anesthetic techniques, technologies, and practice models.'' The paper notes that studies of this size are expensive. None of the studies reviewed meet this standard.

The paper reviewed two studies that compared mortality for anesthesia care furnished by anesthesiologists, and anesthesia care team and nurse anesthetist supervised by a physician. Neither meets the criteria for an adequate study identified in the paper. As the authors note, the first study did not provide statistical analysis of the data. The second study used data now 25 years old and found no statistically significant difference between the groups. Neither study examined the provision of anesthesia furnished independently by CRNAs, the issue of this rule.

The paper suggested a number of reasons for improved anesthesia care including ''new and improved patient monitoring techniques.'' The paper also notes that the ''decline in adverse outcomes occurred at the same time that the number of American trained physicians entering and graduating from anesthesiology residency programs more than doubled (1975–1985).'' The paper suggests that ''the increase in the number of physicians engaged in the practice of anesthesiology is primarily responsible for the dramatic improvement in perioperative outcomes.'' However, the paper also notes that during roughly the same period of time, 1970–1985, the number of active nurse anesthetists doubled.

On the basis of studies which are flawed methodologically, which do not prove causality, and which do not meet the authors' own criteria for rigorous study, the authors nevertheless conclude that ''the presence of board-certified anesthesiologists has been associated with the decline in death and disability commonly attributed to adverse perioperative events.'' The authors' conclusion is not substantiated by their own review and analysis of the literature. Finally, the paper presents no information regarding the issue in the rule or that States are not capable of making decisions regarding requirements for supervision of one State-licensed independent practitioner by another.

As part of the decision to finalize the rule, we considered the feasibility of conducting a study comparing the mortality and adverse outcomes of Medicare patients for anesthesia care furnished by CRNAs with and without physician supervision. However, we concluded that it was not feasible to conduct such a retrospective study. Not only would the low overall anesthesia mortality make it difficult to develop a sufficient sample, but because of the current Medicare rule, there are no cases where CRNAs practice without supervision and thus there would be no data for the key comparison. We also considered the feasibility of conducting a study using data from non-Medicare patients. However, because Medicare's current hospital conditions of participation apply to all patients, here too there would be no data for the key comparison. Finally, we do not believe that it would be wise to conduct a prospective demonstration which would waive State law and prospectively randomly assign patients to study and control groups because it would remove patient choice of anesthesia professional.

Comment: Several commenters felt strongly that anesthesia should be considered a high-risk procedure where mistakes are measured in terms of death and injury. These commenters believe that millions of patients will be at a higher risk for injury without the supervision of board certified anesthesiologists. One commenter noted that without the requirement, no trained physician would be available to respond to any emergency during a case where a CRNA was practicing independently.

Response: If we were to require board certification for anesthesiologists as a hospital CoP it would be a stricter requirement than currently exists for the practice of any other medical specialty subject to our CoPs. Hospitals have been providing anesthesia care without a Federal requirement for board certified anesthesiologists since the inception of the Medicare program. This rule does not change the requirement that hospitals must have physicians available at all times and that all Medicare patients are under the care of a physician as defined in section 1861(r) of the Act. Therefore, the patient's medical and/or surgical care continues to be the responsibility of his or her assigned physician.

Comment: Several commenters wanted to know what had changed since a 1992 HCFA comment that, ''In view of the lack of definitive clinical studies on this issue, and in consideration of the risks associated with anesthesia procedures, we believe it would not be appropriate to allow anesthesia administration by a nonphysician anesthetist unless under supervision by either an anesthesiologist or the operating practitioner.''

Response: As discussed above, there are no definitive studies one way or the other which address this question. The studies we discussed in our 1992 final rule on fee schedules for CRNAs (57 FR 33878, July 31, 1992) have limitations, as does the literature since 1992. Moreover, there is no evidence that an across-the-board physician supervision requirement for CRNAs leads to better outcomes or that there will be adverse outcomes by relying on State licensure laws instead. What has changed since 1992 is our view that it is unnecessary to continue a special Federal preemption of State licensing laws regulating professional practice for CRNAs.

The 1999 IOM Report cites a drop in anesthesia mortality rates from two deaths per 10,000 anesthetics administered in the early 1980's to

about one death per 200,000 to 300,000 anesthetics administered today. Chassin (1998) identifies several studies which note this improvement is a result of ''a variety of mechanisms, including improved monitoring techniques, the development and widespread adoption of practice guidelines and other systematic approaches to reducing error.'' This is an impressive improvement and confirms the soundness of the approach taken in this final hospital CoP, which broadens the flexibility for States and providers, who are much closer to the realities of patient care, to make decisions about the best way to improve standards and implement best practices.

Comment: Several commenters stated that quality of care should be an important consideration in determining the need for physician supervision. Some commenters noted an association between improved anesthesia outcomes and increased numbers of anesthesiologists practicing. Many commenters noted that some CRNAs could function independently, but that others lack the judgement and knowledge to safely provide anesthesia without supervision. Further, commenters point out that CRNAs are more than capable of administering anesthesia on a healthy adult; however, when a patient's health is poor, an anesthesiologist should be involved in the care. Some nurse anesthetists report concern with their ability to deal with anesthetic complications without the availability of an anesthesiologist.

Response: Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is because, as stated in the preamble of the proposed rule, we are committed to changing current regulations that focus largely on procedural requirements, such as the Federal regulation mandating physician supervision of CRNAs. These comments make clear there are a range of factors to be considered (for example, patient types, surgical procedures, technology, and provider settings). Differences between a healthy young patient undergoing minor surgery in a hospital outpatient department and a medically compromised, elderly patient undergoing major surgery in a large teaching facility are so great that a single Federal requirement applicable in every situation is not sensible.

Comment: One commenter noted that the practice of anesthesiology extends beyond the operating room to the Intensive Care Unit (ICU), pain management, and other medical consultation. The commenter believes that the removal of the medical supervision requirement risks removing the anesthesiologist from the practice of anesthesia.

Response: The change in the physician supervision requirement for CRNAs does not affect the anesthesiologist's ability to provide services outside the operating room.

Comment: A few commenters told us they believed it was the Federal government's responsibility to set safety standards for the nation and this rule evades that responsibility. One commenter agreed that CRNAs have a good safety record, but emphasized that they have been under the direct supervision of the anesthesiologist. He believed that eliminating the supervision requirement would cause these positive patient outcomes to occur less frequently. Other commenters agreed that physicians absolutely need to be involved for the practice of medicine to be safe, and this regulation change is in direct violation of this principle. Some commenters noted that the practice of safe anesthesia administration is largely due to better monitoring techniques, technology, improved drugs, and not to greater supervision by a physician. One commenter stated that in combination with improved drugs and techniques, CRNAs will bring greater access to anesthesia services in situations and areas where they are currently limited in their practice because of the physician supervision requirement, thus allowing such delivery of medical services that improve patient health and safety, and provide services to a greater number of people.

Response: We are acutely aware that ensuring patient safety and high quality patient outcomes are the principal considerations in regulating providers. There is no indication that physician supervision of a CRNA affects such outcomes. It is for this reason that we are moving away from a focus on physician supervision, where there is no evidence or data linking this structural requirement to patient outcomes. As previously noted, changing the supervision requirement does not obviate the requirement that every Medicare patient admitted to the hospital be under the care of a physician or doctor of osteopathy. This requirement remains an important component in the hospital CoPs. 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 supervision requirement. This rule does not prohibit anesthesiologist supervision or administration; it simply leaves the decision up to State law or hospital policy.

This rule recognizes the significant improvement in the safety of anesthesia administration made by improved technology and implementation of practice guidelines. As in other areas of health care, new drugs and pharmaceuticals have contributed to improved patient outcomes as well. This underscores the findings in our review of the literature that multiple variables, some interacting in combination with each other, contribute to anesthesia-related patient outcomes.

Comment: We received several comments from beneficiaries who had received anesthesia care from a CRNA and felt comfortable with the service that was provided. They describe their anesthesia experiences as compassionate and thorough, including quality service and attention from these professionals. Many felt their care was excellent. Another commenter noted nurse anesthetists take time to be compassionate and attentive to fears, approaching anesthesia care holistically.

We also received comments from beneficiaries who felt that their care was being compromised for economic reasons by not requiring a doctor to be in charge of their anesthesia. Many reported increased fears during a time when they are most vulnerable, without the guarantee that a doctor will be in charge of their anesthesia care. Many reported that, as senior citizens, they faced more complicated medical and surgical procedures than younger patients and therefore that hospitals should be required to have a doctor in charge of administering their anesthesia.

Response: Patient experiences can be influenced not only by the anesthetist, but the surgeon, the type of procedure, the emergency nature of the procedure, and other factors. We also believe that many Medicare beneficiaries have been receiving anesthesia from CRNAs without being specifically aware of the credentials of the administering professional. We agree that a patient's perception of the safety and concern demonstrated by medical personnel is important but there is no evidence linking safety or better patient outcomes to the Federal requirement for physician supervision.

The change made by this rule is not specific to the patient's status as a Medicare beneficiary but to the participation of the provider in the Medicare program. The increased flexibility gained by this rule will allow hospitals and doctors to make decisions, pursuant to State law, about what is best for patients, reinforcing the primacy of the doctor-patient relationship.

Professional Education and Training

Comment: Several commenters noted the differences in training and education between a CRNA and an anesthesiologist. These differences were considered significant by anesthesiologists, who believe that anesthesia administration is the practice of medicine and should only be performed by physicians. Physician commenters pointed out that anesthesiologists receive in-depth training in physiology, pharmacology, diagnosis, treatment and independent management of patient care. In addition, because they are physicians and have received medical training, anesthesiologists assess a patient's medical condition, as well as plan and administer the anesthetic. One physician stated ''nurse anesthetists are trained to assist anesthesiologists; they are not physicians and are not trained in medical diagnosis and therapy. The lack of medical background prevents the CRNA from being able to diagnose and treat the unexpected, and often serious, reactions that can accompany anesthesia in even the simplest of cases. CRNAs should be considered valued extenders of care but not as substitutes for the expertise of an anesthesiologist.'' Other commenters stated that nurses are trained to follow orders and medical protocols, and are not trained to diagnose and treat. Several anesthesiologists, who had been nurse anesthetists, wrote describing that not until they had medical school training did they understand the full impact of the differences between the education preparing them as nurse anesthetists versus their preparation to practice as anesthesiologists. One commenter stated he believed the regulation should be based on demonstrated formal education. Another physician commenter stated he believed CRNAs were well educated and trained and had good records of performance, but that this was due to their collaboration with doctors, and not their independent management of medical situations.

Some commenters stated, inaccurately, that the postgraduate training of nurse anesthetists is unique in that, after a minimum of a bachelors degree in nursing, the nurse anesthetist student is required to have at least two years of practical experience in a critical care setting before advanced formal education in anesthetic administration. They stated that this advanced training prepares the nurse anesthetist to provide the full range of anesthesia services, independently. Several commenters noted that nurse anesthetists must be board certified by successfully completing the National Certification Examination. Other commenters felt that the knowledge and expertise in nurse anesthesia care is equivalent to the preparation provided physicians. Some commenters reminded us that the Federal supervision requirement has been the only obstacle to independent practice, and that otherwise nurse anesthetists are licensed and trained to practice independently. One CRNA stated he did not agree with the contention that educational differences between CRNAs and anesthesiologists are sufficient reasons to place practice restrictions on CRNAs.

Response: Education and training requirements for CRNAs vary among the States. Decisions about appropriate and necessary education and training for health professionals are made by States and educational institutions in compliance with education accreditation standards. Professional schools, both medical and nursing, are accredited by educational organizations with specific standards for curriculum content. Evidence of graduation from an accredited school is part of a State's licensing and certification requirements, independent of Federal regulation. Anesthesia administration by nurse anesthetists has a long history in this country, including a level of independent practice in Department of Defense hospitals. We cannot agree that anesthesia administration is the practice of medicine and therefore can only be done after medical school training. Moreover, the rule does not allow any provider to practice outside the parameters of his or her professional license.

We also believe that this rule is consistent with both sides of this argument as reflected in the comments. The added flexibility and shared responsibility allows each health professional to practice within his/her licensed scope of practice without an across-the-board Federal requirement limiting any collaborative, team or independent practice.

Comment: Additional commenters claimed significant variation among program requirements in nurse anesthetist training. Some of these commenters cited an article from the June 1996 Journal of the American Association of Nurse Anesthetists, identifying that more than one-third (37 percent) of nurse anesthetists do not have bachelor's degrees, less than a quarter (22 percent) have a master's degree, and less than 1 percent have a Ph.D. In comparison, the writers note, all anesthesiologists have an undergraduate degree, 4 years of medical school and specialty training in anesthesiology.

Response: We recognize that education and training requirements vary among the States. As previously noted, States are well skilled at deciding requirements related to health care professional licensing. Our change in the hospital rule deferring to State oversight is not an endorsement of one health professional over another. It is not a rule that defines medical or nursing standards of practice or educational preparation. The rule merely allows the authority (that is, States) whose traditional role it is to make such determinations (for example, which health care professional is trained to provide which health care services) to do so in the case of anesthesia administration.

Comment: There was some concern expressed that eliminating the Federal requirement for supervision would result in decreased physician involvement in the training of CRNAs. One commenter speculated that this provision would reduce the incentive for a physician to specialize in anesthesiology and physician-administered anesthesia would soon vanish.

Response: We disagree that eliminating the Federal supervision requirement will necessarily lead to physicians making decisions about practice specialties, other than anesthesiology. This rule change is not a judgment about the value or contribution of one health professional or another. We believe that with greater staffing flexibility, opportunities for collaboration between physicians and nurse anesthetists will increase based on individual patient needs, hospital characteristics, and an increasing ability to implement best practice protocols.

Comment: A few commenters thought that eliminating supervision by the anesthesiologist will limit the choice of anesthesia modalities and deprive patients of an appropriate anesthesia plan. These commenters stated that CRNAs are not trained in various types of nerve blocks and/or the use of certain devices. These additional skills are necessary to care for critically ill patients.

Response: This change in regulatory approach does not permit any licensed independent health care provider to practice beyond his or her licensed scope of practice. While we acknowledge there will continue to be medical interventions or treatments that fall under the practice authority of a medical licensee, these determinations are not, and never have been, made by Federal regulation, but by States, with

input from, and consultation with, licensed health professionals. Typically these decisions on practice issues fall to provider credentialing, licensing or certification authorities. All areas of health care are constantly faced with implementing new technologies, procedures, drugs, biologicals, or devices. As these new techniques become available we believe it is the responsibility of States, hospitals, and professional organizations to implement standards for training and assuring practice competency. In addition, we have no evidence to indicate that eliminating the Federal supervision requirement for CRNAs will limit the choice of anesthetic modalities or deprive patients of appropriate anesthesia plans.

Comment: There were a few comments stating that the evolution of non-physician practitioners is expanding through the use of well-trained and very capable professionals. Advanced practice nurses represent part of the movement to broaden access, increase efficiency and maintain health care quality. One commenter applauded our efforts to eliminate restrictions preventing full utilization of these highly trained and qualified health professionals.

Others wrote in with concerns that this rule was opening the door to allowing other independent health professionals to engage in unsupervised practice in hospitals and through other providers regulated by us. Some of these commenters pointed to increasing activity at the State level to expand scope-of-practice laws for nonphysicians. Examples, such as psychologists seeking prescribing authority and complementary and alternative medicine practitioners lobbying to expand their professional practice rights, have been used to argue that lesser-trained professionals are attempting to practice medicine without the appropriate training or supervision. They point out that these are more examples of loosening regulatory safeguards over the practice of medicine and patient care.

Response: States have an excellent track record of protecting patient health through their own regulations. We respect State control and oversight of health professionals by deferring to State licensing laws to regulate professional practice. We have determined that there is no need for continuing Federal preemption of State laws by maintaining a requirement for physician supervision of CRNAs as a special case. There is no evidence that States are any less concerned with ensuring safety and quality than the Federal government, especially when it comes to the health and safety of their citizens. In fact, our evidence-based, outcome-oriented standards establish a shared commitment between us, the States, and Medicare providers to ensure safe, quality anesthesia administration. States have a good track record in determining best practices. In fact, it is at the State level where most direct input by health professionals into scope-of-practice licensing laws takes place.

Additionally, we believe that independently licensed health professionals have served a valuable role in expanding access to, and maintaining quality in, many health services. The change in the Federal requirement for physician supervision is not an endorsement of any health profession, model of care delivery, or promotion of a specific standard of care. It is a change in approach to regulatory oversight that recognizes the worth of State control in meeting regional/local needs.

Operating Surgeon Providing Physician Oversight

Previous regulation required physician supervision by either an anesthesiologist or the operating surgeon. We received many comments from surgeons asking about the surgeon's liability as well as questions about who would be considered in charge of the patient's care.

Comment: One surgeon noted that he is dependent on the anesthesiologist as a consultant to provide care and recommendations concerning his patient. Other surgeons did not want responsibility for the anesthesia care of their patients when they were not trained in anesthesia. One commenter stated ''surgical residency programs have intensified training in surgical technical skills, and decreased emphasis on anesthesiology training, leaving such matters to the consultant in Anesthesiology. As a result, [the surgeon's] ability to supervise the CRNA has declined.'' This commenter asserted this should encourage us to require CRNA supervision by an anesthesiologist only. One anesthesiologist asked whether he would be responsible for anesthesia management done prior to his consultation.

Response: This final rule does not require supervision, direction, or oversight of any independently licensed practitioner administering anesthesia by the operating surgeon. The surgeon would still be able to involve an anesthesiologist as a consultant or in any other capacity. This rule does nothing to restrict that relationship. CRNAs, as well as anesthesiologists, are accountable for their own practices, the care they deliver, patient outcomes, as well as insurance liability coverage.

Comment: A few commenters stated there will be increasing pressure on surgeons, from hospitals, CAHs, and ASCs, to eliminate the anesthesiologist. Another commenter wrote that he believes if we allowed this change, it would not be long before private insurers would refuse to pay physicians no matter how sick the patient or complex the procedure.

Response: This rule governs participation requirements for hospitals, CAH, and ASCs participating in the Medicare program. It does not eliminate, restrict, or in any way limit the practice of any practitioner. In addition, an insurance company cannot establish health professional practice rules that are in conflict with State licensing laws.

Comment: We received several comments asserting the physician supervision requirement was responsible for surgeons choosing not to practice in some settings because they do not want the liability associated with the supervision responsibility. One commenter noted that one possible result of lifting the Federal supervision requirement is that more surgeons may be willing to practice in geographical areas they previously would have avoided partially because they did not want to be responsible for supervising the CRNA. Some believed the rule change will alleviate fears of surgeons who were concerned about taking on increased legal liability. Others noted that removing the supervision requirement afforded greater flexibility for surgeons and hospitals to choose their anesthesia providers without fear of increased liability.

Response: The rule makes no legal change in the scope of malpractice liability, traditionally a State issue. Our rule, permitting any State licensed health professional permitted by the State to administer anesthesia would not definitively affect any provider or professional the same way in all States. Because both scope-of-practice and malpractice liability differs from state to state, as a general matter, any professional who has contact with the patient could conceivably be held liable for personal injury, depending on the facts and circumstances of the case and on the State's laws. This issue is not the subject of this rulemaking.

Rural Issues

Comment: We had many comments on this provision relative to the practice of nurse anesthetists in rural areas. Even

many physicians supported the changed supervision requirement in rural areas where access to anesthesiologists is limited. Some comments from surgeons practicing in small communities noted they have worked solely with CRNAs for all procedures, and they never felt they had a need for any additional supervision, regardless of the medical situation. They further point out that without nurse anesthetists willing to practice in medically underserved areas, no one would be available to administer anesthesia.

However, other physician commenters noted that under current regulation, even without a supervising anesthesiologist, the operating surgeon provides supervision to the nurse anesthetist. One commenter noted, ''the administration of anesthetics by nurse anesthetists in rural communities of this country is a condition of necessity, not design, since these areas are generally underserved by physicians.'' The commenter disagrees with proposing a national standard based on these criteria.

Response: The intent of this rule is not to limit or prohibit any anesthesia care model. We are changing a thirty year old policy to more accurately reflect demands of current practice, variations in hospital, CAH or ASC, patient characteristics, resource management, technology, and ever-increasing medical knowledge. We concur with the experience of the commenters who state that 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. We disagree, however, that the new rule, by itself, will guarantee an adequate supply of CRNAs in rural settings. A patient population's medical or surgical needs; hospital, CAH, or ASC characteristics; State practice laws, etc. are all factors contributing to decisions of CRNAs about where to practice. These variables exist in rural as well as other geographic areas.

Comment: A few commenters believed we were erroneous in our assumption that allowing independent practice of CRNAs would increase access to needed medical procedures in rural areas. One commenter asserted we were wrong in our assumption that there is a problem of access to care in rural areas. CRNA commenters noted that CRNAs administer anesthesia unsupervised by an anesthesiologist in approximately 70 percent of rural hospitals within the United States, providing a full range of anesthetic services (for example, surgical, obstetrical, and trauma stabilization).

Response: Without CRNA availability in certain areas there would be limits on the types of surgical interventions or procedures that could be performed in those areas, because no anesthesia professionals other than CRNAs would be available.

Comment: Several people asked that we create a rural carve-out for CRNA independent practice. Some of these commenters agreed with keeping the requirement for operating physician supervision, while others supported full independent practice. Still others, even though in agreement with a rural carve-out, wanted us to create a requirement for supervision by an anesthesiologist wherever there were no shortages of this physician specialty. Additionally, these commenters wanted assurance that patient care outcomes would continue to be monitored so that all patients would be receiving the care they deserve.

Response: The purpose of the change in the requirement is not simply to respond to the needs of physician shortage areas. We gave full consideration to this option but decided that the importance of increased flexibility, decreased burden, and broadened implementation of best practice protocols were important for hospitals in all geographic settings. We believe there is no reason for an across-the-board Federal requirement that could potentially limit development of new practice models of anesthesia delivery, or interfere with progress in promoting practices that improve patient outcomes.

There are additional mechanisms in place to support monitoring of patient outcomes. There are other hospital standards and oversight activities that address how care is delivered and identify mechanisms hospitals must have in place to assure patients receive safe, quality care.

Comment: One commenter stated that by expanding CRNA independent practice outside of rural areas, increased competition would occur with anesthesiologists for jobs in better served areas and would result in CRNAs choosing not to locate in less desirable and under-served areas. This commenter supported a rural carve-out for fear that without such a carve-out, these underserved areas would again experience access problems. Another commenter mistakenly believed that requiring physician supervision would result in CRNAs working without payment, leading small community operating rooms to close.

Response: CRNAs are paid under the CRNA fee schedule. The CRNA may furnish the service under the ''medical direction'' of a physician, usually the anesthesiologist, or the CRNA may furnish the entire anesthesia service without medical direction, while still under the supervision of the operating surgeon. Payment rules for CRNAs, as well as for physician anesthesiologists, do not change as a result of this rule.

This issue of health professional shortage has always been present but there is no way to predict that this will be a definite outcome of the rule change. The Congress, the Department of Health and Human Services, and the States continue to address the issue of health professional shortages through a variety of mechanisms, including increasing educational grants and loans for those who choose to practice in designated critical shortage areas.

Pre- and Post-Anesthesia Evaluations

Comment: Several writers cited the importance of the pre-anesthesia evaluation as critical to prevention of complication during and after a procedure. Many of these commenters felt that only a physician with detailed knowledge of medicine has the ability to make a reasoned, informed judgment about the medical state of a patient. Other commenters noted that in addition to the pre-anesthetic evaluation, all peri-operative assessment and care requires physician oversight. One commenter pointed out that anesthesia complications might be a result of several factors, including inadequate pre-anesthetic preparation, severity of concurrent disease, inappropriate monitoring and lack of post-anesthetic follow-up care. Another commenter stated this process is more accurately described as ''pre-procedure assessment'', indicating the importance of thorough consideration of the patient's medical needs.

Response: We agree with commenters that a variety of factors and contributing variables influence surgical and anesthesia outcomes. Our literature review and analyses of comments confirms our conclusion that interactions among and between these variables are difficult to isolate in terms of their individual effects on outcomes. Education and training programs for CRNAs include pre- and post-anesthesia care. Pre- and post-anesthesia assessment and monitoring are scope-of-practice issues determined by each State as it considers education and training requirements for professional licensing.

We are sensitive to the debate between physician anesthesiologists and nurse anesthetists regarding what

constitutes the practice of medicine with regard to anesthesia administration. States have handled these issues through laws and health professional practice acts. Questions of who is properly trained to do a pre-anesthesia evaluation, care for a patient in recovery, order pain medication, or perform a procedure that results in conscious sedation of a patient, have all faced States when they adopted professional licensing laws. This rule change does not prohibit collaboration between medical professionals including surgeons, nurse anesthetists, and/or anesthesiologists in the total care and treatment of any patient in the hospital. As expanded scope-of-practice issues are debated at the State level, we expect continued involvement by medical and health professionals to ensure best practices and protocols are incorporated in final decisions about which professionals meet the required training and education to perform any particular service.

Collaboration and Anesthesia Team Approach

Comment: Several commenters explained that this rule would not significantly change the manner in which CRNAs currently work. One commenter noted that ''anesthesia always has been and always will be given only as an adjunct to a surgical or diagnostic procedure. Collaboration must occur with the primary physician no matter if the anesthesia is provided by a physician anesthesiologist or a nurse anesthetist.'' Other commenters reaffirmed this by pointing out that collaboration is intrinsic to the practice of anesthesia administration, and therefore an explicit requirement of supervision is at best unnecessary. Others brought to our attention that State laws that require supervision vary in their definitions and in many cases define supervision as collaboration rather than direction.

Several anesthesiologists commented in support of the collaborative, team approach to anesthesia delivery. Commenters stressed the valuable and knowledgeable assets CRNAs are to the anesthesia team. These commenters expressed some concern that the rule will destroy the longstanding concept of the anesthesia care team, making it less likely hospitals will take advantage of the skills of the nurse anesthetist and the medical training of the anesthesiologist.

Response: As we have said, this rule makes no judgment in support of one model of care over another. In addition, the rule does not prohibit collaboration or teamwork during anesthesia administration. We believe the rule will promote best practices and encourage professional collaboration, in an effort to improve anesthesia care delivery and patient outcomes. We are pleased with the comments in recognition of the valuable contribution made by both professionals to the care of patients during anesthesia administration.

Comment: One commenter wrote that in most settings patient care is a team effort, and the current supervision requirement encourages polarization rather than collaboration. This commenter noted that when CRNAs have problems or questions about patient care they seek consultation with colleagues. Other commenters stated that the removal of the requirement provides surgeons, medical physicians, and others who perform diagnostic or surgical procedures freedom to collaborate or choose the anesthesia provider best suited to the procedure and the patient's needs. Additionally, many who supported the change in the rule believe that only a few CRNAs in certain circumstances would want to practice without supervision. They felt that both nurses and anesthesiologists preferred a team model of practice.

Two commenters stated that dentists, some physicians, and podiatrists work in settings where collaboration with an independent nurse anesthetist better suits the needs of the patient. They particularly noted the practice by nurse anesthetists of staying with patients for the entire duration of the procedure and through discharge from surgery as being helpful.

Similarly, we had several physicians state that the average healthy person can be safely managed by a CRNA. However, they contend a person with multiple medical problems or those undergoing complex or high-risk surgery should have a physician evaluation and medical direction during his or her care. The commenters believed that with this type of distinction in care, both parties would work together to deliver high quality anesthesia.

Response: One of the limits to requiring an overarching, across the board Federal requirement for supervision is the problem it creates for providers to tailor care to the needs of patients. These comments reaffirm what we have previously noted about the wide variability in patient presentations (for example, medical factors, type and nature of procedure, age, health, etc.) and how these variables influence clinical decisions about anesthesia administration. This rule change removes these unnecessary restrictions.

Cost to the Medicare Program

Comment: We received many comments on the financial motivations of various types of professionals for taking a position on one side of this issue or another. Many of the 20,000 comments accused one professional group or another of lacking concern for safety or adding additional burden to the health care delivery system for the sole purpose of financial gain or practice monopoly. We also received comments asserting that our motivation was to save money payable through the Medicare and Medicaid programs at the cost of quality anesthesia services. Those who support the change note that it removes a financial disincentive to use nurse anesthetists by no longer requiring payment to two professionals. They feel nurse anesthetist will be more efficient and expand a hospital's ability to provide services to more patients.

Many nurse anesthetists report having full responsibility for administering an anesthetic and caring for a patient while the anesthesiologist is somewhere else in the surgical area having no interaction with the patient. They note CRNAs are able to provide the same quality service at a lower cost, without the additional fee to an anesthesiologist for providing supervision. One commenter expressed support for the change as one that will greatly facilitate the use of cost-effective, outcome-based providers, noting ''Unnecessarily mandated layers of supervision ultimately add cost to care, and yet have never documented any benefits.'' Many commenters wrote us with specific examples of how Medicare charges and costs would decrease as a result of the rule.

There was a common misunderstanding among many commenters that this change meant that Medicare patients would be forced to receive a lesser level of care because the rule changed the reimbursement for Medicare patients. One commenter asked, ''Why would HCFA institute payment procedures that decrease the level of care provided to Medicare and Medicaid patients in the name of flexibility?'' Another stated this rule proposes a double standard in that Medicare and Medicaid patients would not have the benefit of a physician's expertise to ensure their safety during critical peri-operative time.

Response: This rule does not change the payment policies for anesthesia services. Medicare payment rules remain the same. CFR section 415.110(a) requires that the anesthesiologist perform specific activities for each patient in order to be paid for providing

''medical direction.'' It must be emphasized that the ''medical direction'' rules are rules for payment of the physician's service under the physician fee schedule. The physician fee schedule payment per service is related to the amount of physician work associated with the service. Thus, the medical direction requirement must establish some level of physician work that is reasonable in relation to the allowance recognized for the service. The ''supervision'' of the CRNA by a physician, usually the operating surgeon, is not a separately payable service for the surgeon. The payment for this service is considered a part of the global surgical fee paid to the surgeon.

Because this rule does not affect payment , the determination about supervision is not specific to a Medicare beneficiary. These rules apply to all patients receiving anesthesia services in Medicare participating hospitals, CAHs, and ASCs, thus Medicare patients would not receive a different level of care from non-Medicare patients and therefore, does not mean different care for Medicare or Medicaid patients. The rule is specific to the provision of anesthesia services in a Medicare participating hospital, CAH, or ASC, and applies to all patients.

Comment: Several commenters who opposed this provision warned that costs to the Medicare program will increase as a result of this rule. Many believed that, although there will be no immediate effect since payment remains the same, costs would increase in the long term because of resulting anesthetic complications and malpractice. Others told us they believe anesthesiologist consultations will increase because some of these services are included in the anesthesia administration fee but as consultants, anesthesiologists would have to charge separately for these services.

Response: Neither costs to the Medicare program nor payment to different professionals was part of the decision to change the hospital CoP for anesthesia services. The fears of long term negative outcomes, increasing medical complications and higher malpractice insurance premiums, related to professional type, are unwarranted, based on our review of the literature. This rule will not prohibit consultation, physician supervision, or anesthesiologist administration of anesthesia where State and/or hospital by-laws require it. Whether payment can be made for consultations will be determined by the usual physician coverage and payment rules.

General

Comment: We received many anecdotal comments from beneficiaries, describing both positive and negative experiences during anesthesia, such as, the importance of a caring, well-trained professional who gives the needed patient attention, and answers the patient's questions. Rarely did the comments identify the professional by credentials.

Response: These reports are important in that they confirm our commitment to patient-centered, outcome-oriented approaches to regulating Medicare participating providers.

Comment: Several certified anesthesiology assistants (AAs) expressed concerns about how the rule might affect their practice. Since the rule allows anesthesia to be administered only by a person licensed by the State to do so, they question whether this requirement would prohibit their practice. Some of the AAs recommended that we omit the term licensed and allow States to determine whether licensure is required at all to practice anesthesia.

Response: We do not agree with the comments that no State licensure should be required for anesthesia health professional practice. As noted, this rule defers to State scope-of-practice laws which identify health professionals that are allowed to administer anesthesia. Under this rule, AA s would be allowed to practice within their scope-of-practice specified by State law.

Comment: One commenter recommended that we require a CRNA to disclose that a nurse, not a doctor, would be providing anesthesia care and that if the patient desired to choose another provider his or her request would be honored. Other commenters stated that this rule is being promulgated without adequate input from patient advocate groups and without regard to how it might affect patient care. They believe that this rule serves special interests and that patient interests have not been adequately considered.

Response: The request for an anesthesia provider is usually made by the surgeon or physician in charge of the patient's care. We believe the flexibility allowed through this rule change will enable physicians to make the best and most suitable choice for their patient's characteristics, medical and anesthesia needs. Patients are always free to ask about the qualifications of any practitioner providing care, including doctors, nurses, therapists, surgeons, or anesthetists.

We received comments regarding this proposal from patient advocates and individual Medicare and Medicaid beneficiaries as well as providers on both sides of the issue. We agree that safety and quality patient outcomes should be the principal consideration in regulating providers. It is exactly this focus which has led to the regulatory change in supervision of CRNAs.

Comment: Several commenters pointed to other ways in which the Federal government supported nurse anesthetists, citing, as examples, Federal funds under Title VIII of the Public Health Service Act and Medicare Education Funds. One commenter wrote that nurse anesthetists received approximately $2.7 million dollars per year for student trainees, faculty fellowships, and new program startup money.

Response: As previously noted, this rule is not intended to endorse one health care professional over another. It is intended to recognize the value in flexibility for providers when making decisions about how to best manage resources to ensure access to quality health services.

Comment: We received a few comments from nurse anesthetists who believed that implementation of this rule would be easy in those parts of the country where CRNAs have practiced and are treated with respect. Some of these commenters identified difficulty in achieving professional courtesy and referrals from doctors who did not recognize their skills and abilities.

Response: To the extent that this rule provides opportunity for greater flexibility for providers and increased access to quality health care for patients, we hope that this will occur. It is not our goal in this rule to prescribe, or to limit, which health care professionals may collaborate, supervise or work independently. We do, however, hope to decrease barriers to access, increase efficiency, and encourage improved models of safe anesthesia delivery. We believe that is best accomplished by sharing the responsibility with States and providers.

III. Provisions of the Final Regulations

We are amending § 482.52(a)(4) of the current hospital CoPs and § 485.639(c)(1)(v) of the current critical access hospitals CoPs, to codify requirements for who may administer anesthesia under Subpart D—Standard: Anesthesia Services. This change is also reflected in a conforming amendment to the ASC Conditions of coverage at § 416.42(b)(2). This final regulation eliminates a Federal requirement for physician supervision and defers to

States the determination of which licensed practitioners are allowed to administer anesthesia.

IV. Collection of Information Requirements

This document does not impose information collection and record keeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This rule is not considered to have a significant economic impact on hospitals and, therefore, is not considered a major rule. There are no requirements for hospitals to initiate new processes of care, reporting, or to increase the amount of time spent on providing or documenting patient care services. This final rule will provide hospitals with more flexibility in how they provide quality anesthesia services, and encourage implementation of the best practice protocols.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. For purposes of the RFA, all non-profit hospitals, and other hospitals with revenues of $5 million or less annually are considered to be small entities. Some critical access hospitals and some ASCs with revenues of $5 million or less annually are also considered to be small entities. Individuals and States are not included in the definition of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. This rule places no additional cost requirements for implementation on the governments mentioned. It will allow CRNAs to practice without physician supervision where State law permits or to be supervised by a physician where such oversight is required by State law. This change is consistent with our policy of respecting State control and oversight of health care professions by deferring to State licensing laws to regulate professional practice. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule imposes no direct compliance costs on State or local governments.

B. Anticipated Effects

1. Medicare and Medicaid participating hospitals, CAHs, and Ambulatory Surgical Centers will defer to State licensing laws in determining which health professionals are permitted to administer anesthesia. In addition, these facilities are free to exercise stricter standards than required by State law.

2. First, it must be noted that this final rule does not change the Medicare payment policies for anesthesia services. There is an important payment distinction between the medical ''direction'' requirements and the physician ''supervision'' requirement. Payment made by Medicare on a fee schedule basis is not payment for ''supervision'' but rather payment for ''direction'' and the payment per service is related to the amount of physician work associated with the service.

Second, economic effects on individual health professionals as a result of this rule change will be influenced by other factors. Because the final rule defers to State licensing laws, the impact on either physician or CRNA income from billed services will be determined by each States' laws. State laws vary widely in both the definition and degree of physician supervision and oversight required of CRNAs. In addition, some State laws leave the determination up to individual hospital, CAH, or ASC medical staff by-laws, resulting in a financial impact that is different depending on where the physician or CRNA provides the services. In any of these situations the potential impact might include an increase or decrease in billed services by CRNAs practicing alone, in billed services by physicians practicing alone, in billed services by physicians providing medical direction in collaboration with CRNAs, as well as the possibility of no change in billed services by either provider. In some of these cases, where there is decreased physician billing, there may be increased savings to third party payers.

Finally, the flexibility resulting from the rule change could provide increased access to services in some areas, and broaden opportunity for providers to implement professional standards of practice that improve quality and promote more efficacious models of care delivery.

3. This rule increases flexibility in the provision of anesthesia services for Medicare and Medicaid hospitals, CAHs, and ASCs. It removes the burden of implementing a Federal requirement for physician supervision of CRNAs in all cases. The rule change will allow hospitals, CAHs, and ASCs the flexibility, within the authority of State licensing laws, to implement best-practice protocols in providing anesthesia services most associated with positive patient outcomes. Moreover, hospitals are free to exercise stricter practice standards. As discussed in the preamble of the December 19, 1997 proposed rule, this provision does not lend itself to a quantitative impact estimate, and we do not anticipate a substantial economic impact either in costs or savings.

C. Conclusion

We are changing the current across-the-board Federal requirement for physician supervision of CRNAs to allow State control and oversight through professional licensing laws. This change applies to all Medicare and Medicaid participating hospitals, CAHs, and ASCs. Our decision to change the Federal requirement for supervision of CRNAs applicable in all situations is, in part, the result of our review of the scientific literature which shows no overarching need for a Federal regulation mandating any model of anesthesia practice, or limiting the

practice of any licensed professional. The clinical evidence indicates anesthesia outcomes have improved substantially in recent years such that anesthesia is a relatively safe procedure. Both our literature review and comment analysis made clear that there is such a range of variables and influences to be considered (for example, patient types, surgical procedure, and/or availability of technology) that a single Federal requirement applicable in all situations is unnecessary and may actually interfere with factors that promote quality patient outcomes.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VI. Federalism

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does significantly affect the rights, roles, and responsibilities of States. This final rule removes the Federal guideline that requires CRNAs to be supervised by a physician and allows the laws of the States to determine which practitioners are permitted to administer anesthetics and the level of supervision required.

List of Subjects

42 CFR Part 416

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR Chapter IV is amended as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for Part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

2. Section 416.42 is amended by revising paragraph (b) to read as follows:

§ 416.42 Condition for coverage—surgical services.

* * * * *

(b) *Standard: Administration of anesthesia.* Anesthesia must be administered by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

3. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

Subpart D—Optional Hospital Services

4. Section 482.52 is amended by revising paragraph (a) to read as follows:

§ 482.52 Condition of participation: anesthesia services.

* * * * *

(a) *Standard: Staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered by only a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

5. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395 (hh)).

Subpart F—Critical Access Hospitals (CAHs)

6. Section 485.639 is amended by revising paragraph (c) to read as follows:

§ 485.639 Condition of participation-surgical services.

* * * * *

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 5, 2001.

Robert A. Berenson,

Administrator, Health Care Financing Administration.

Approved: January 10, 2001.

Donna E. Shalala,

Secretary.

Note: This list of references will not appear in the Code of Federal Regulations.

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