obligations must submit the output in the form of an electronic file. * * * * * * * * * *

Signed at Washington, DC, this 7th day of November, 2001.

Charles S. Ciccolella,

Deputy Assistant Secretary, Veterans' Employment and Training Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 416, 482, and 485

[CMS–3070–F]

RIN 0938–AK95

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), 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 Surgical Services Condition of Coverage for Ambulatory Surgical Centers (ASCs), and, with its publication, withdraws the January 18, 2001 final rule (66 FR 4674). This final rule maintains the current physician supervision requirement for certified registered nurse anesthetists (CRNAs), unless the Governor of a State, in consultation with the State's Boards of Medicine and Nursing, exercises the option of exemption from this requirement consistent with State law.

DATES: The rule published in the **Federal Register** on January 18, 2001 (66 FR 4674) was delayed at 66 FR 15352 (March 19, 2001) and was further delayed at 66 FR 27598 (May 18, 2001) is withdrawn as of November 13, 2001. The amendments set forth in this final rule are effective November 13, 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 a proposed rule entitled, ''Hospital Conditions of Participation, Provider Agreements and Supplier Approval,'' (62 FR 66726) in the **Federal Register**. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. We proposed, among other things, to let State law determine which professionals would be permitted to administer anesthetics, and the level of supervision required for practitioners in each category, recognizing States' traditional domain in establishing professional licensure and scope-of-practice laws. Policy surrounding the proposal was based on the principle that States traditionally regulate practitioner scope-of-practice, and was also based on the lack of evidence to support maintaining a special Federal requirement for physician supervision of CRNAs that would have the effect of superseding State requirements. We also stated that a fundamental principle was to facilitate flexibility in how a hospital would meet our performance expectations, and to eliminate structure and process requirements unless there was evidence that they improved desired outcomes for patients.

The final rule was published on January 18, 2001 (66 FR 4674) and was to have been effective March 19, 2001. In accordance with the proposed rule, the January 2001 final rule changed the physician supervision requirement for CRNAs furnishing anesthesia services in hospitals, ASCs, and CAHs. Under that rule, State laws would control which professionals would be permitted to administer anesthesia and the level of supervision required for CRNAs. It did not prohibit, limit, or restrict in any way the practice of medicine by a physician or anesthesiologist. Hospitals, ASCs, and CAHs retained the ability to exercise stricter standards than those required by State law.

On March 19, 2001, the effective date was delayed 60 days in accordance with the memorandum to the President from the Chief of Staff, dated January 20, 2001, and published in the **Federal Register** (see 66 FR 15352). On May 18, the rule was further delayed for 180 days, until November 14, 2001, in order to explore alternatives for implementation (see 66 FR 27598). In reviewing the January 2001 final rule, we identified two important questions that were not raised and thus not addressed previously.

- One question concerned the States' reliance on Medicare physician supervision requirements in establishing State scope-of-practice laws and monitoring practices. In some cases, State laws and regulations may have been written with the assumption that Medicare would continue its longstanding policy requiring physician supervision of the anesthesia care provided by CRNAs. Eliminating Medicare requirements now could change supervision practices in some States without allowing States to consider their individual situations. In the absence of Federal regulations, we were concerned that States might have promulgated different laws or different monitoring practices.
- The second question was whether a prospective study or monitoring should be undertaken to assess the impact in those States where CRNAs practice without physician supervision. The literature we reviewed 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. However, in the absence of clear research evidence it is impossible to definitively document outcomes related to independent CRNA practice.

Both were legitimate implementation questions; thus, in addition to delaying the effective date of the January final rule, we published a new proposed rule on July 5, 2001 (66 FR 35395), which proposed an alternative method for implementing the independent practice proposal in lieu of proposing an immediate removal of the requirement. Our alternative proposal was to—

(1) Establish an exemption from the physician supervision requirement by recognizing a Governor's written request to us attesting that, after consultation with the State's Boards of Medicine and Nursing on issues related to access to and the quality of anesthesia services, and consistent with State law, he or she is aware of the State's right to an exemption from the requirement and has determined that it is in the best interests of the State's citizens to exercise this exemption, and

(2) Have the Agency for Healthcare Research and Quality (AHRQ), with input from HCFA and that of other stakeholders, including anesthesiologists and CRNAs, design and conduct a prospective study or monitoring effort to assess outcomes of care issues relating to CRNA practice and involvement. One approach that we sought comment on was to create a voluntary registry that could prospectively monitor these practices.

The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the *State Operations Manual* (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore are not routinely surveyed for compliance by the SAs.

C. Recognizing State Laws and Professional Scope of Practice

The Congress has specified which non-physician health professionals may receive separate payment for their professional services (such as CRNAs and nurse practitioners). In addition, the 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. This rule establishes a shared commitment to quality care among States, Medicare providers, and us. States 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 conduct a review of 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, by allowing governors to exercise their ability to opt-out of the supervision requirement.

II. Provisions of the Proposed Anesthesia CoP

We proposed several changes to the January 18 final rule that was to have become effective on November 14, 2001. The proposed changes were included in our proposed rule published on July 5, 2001 (66 FR 35395) and affected the physician supervision requirements for certified registered nurse anesthetists furnishing anesthesia services in hospitals (42 CFR 482.52), critical access hospitals (42 CFR 485.639), and ambulatory surgical centers (42 CFR 416.42) that participate in the Medicare and Medicaid programs. Under the final rule, the current physician supervision requirement would be maintained, unless the governor of a State, in consultation with the State's Boards of Medicine and Nursing, exercises the option of exemption from this requirement, consistent with State law. These proposed changes are an integral part of our efforts to improve the quality of care furnished through Federal programs, while at the same time recognizing a State's traditional domain in establishing professional licensure and scope-of-practice laws. It will give States the flexibility to improve access and address safety issues.

We solicited comments on whether a prospective study or monitoring should be undertaken to assess the impact of those states where CRNAs practice without physician supervision, or where physicians practice without the assistance of CRNAs.

III. Analysis of and Responses to Public Comments

We received over 28,500 comments on the proposed anesthesia requirements. These comments were from hospitals, professional organizations, accrediting bodies, practitioners, and other individuals. Summaries of the public comments received and our responses to those comments are set forth below.

A. Outcome Study/Registry

We asked for comments on whether a prospective study or monitoring should be undertaken to assess the impact in those States where CRNAs practice without physician supervision, or where physicians practice without the assistance of CRNAs.

Comment: Commenters were in favor of, and supported our efforts to undertake a prospective anesthesia outcome study. Overwhelmingly, commenters expressed that a study was preferred over a registry, stating that a study would settle many issues with a greater degree of certainty than the registry as a registry would not yield sufficient scientific data. The majority of commenters were opposed to a voluntary registry, stating this method of study carries a heavy bias and would not yield definitive scientific data for use by CMS and the nation's governors. However, there were a large number of commenters that thought a study was unfair, discriminatory (assuming it would exclusively study CRNA practice), expensive, and time consuming. Alternatives were offered such as studying the impact of the removal of the requirement that physicians supervise CRNAs in those States that have opted out of the Federal requirement.

Response: We have chosen not to pursue a registry at this time. Instead, AHRQ will conduct a study of anesthesia outcomes in those States that choose to opt-out of the CRNA supervision requirement compared to those States that have not.

Comment: One commenter questioned the ethics of the proposed study, and asked if patients should be requested to give informed consent for excluding a physician anesthesiologist from their care.

Response: We are not proposing to carry out any independent demonstration, which affects patient choice regarding anesthesia professionals. The study would rely on data collection from practices in use in

the States, according to State law and hospital policy.

B. Boards of Medicine and Nursing

In the proposed rule, we proposed that the governor must consult with the State's Board of Medicine and Nursing in determining if it is in the best interest of that particular state to exercise the option of exemption from the physician supervision requirement.

Comment: Overall the majority of commenters questioned the extent of involvement of the Boards of Medicine and Nursing, and requested clarification and procedures detailing the means by which Boards of Medicine and Nursing act to advise the governor under the rule. Commenters stated that if implemented, this would create an extremely difficult political situation because many governors will not want to be involved in battles between nurses and physicians, or, potentially, battles between nursing and medical boards. Commenters also stated that such a consultation should involve more than a perfunctory communication with the State boards, and said that ''ideally,'' a governor and the State boards should be required to all agree to opt-out, while some commenters suggested the need for governors to obtain concurrence from only the Board of Medicine. In the absence of concurrence, some commenters suggested, at a minimum, the Boards should be required to provide written comments on a governor's petition, which should be available for public inspection. Commenters opposed to the proposed rule, urged CMS to reconsider if there is any useful purpose in the governor consulting with these entities.

Response: The proposed consultation with the Boards of Medicine and Nursing is to ensure appropriate involvement of parties on both sides of the issue. We purposefully were not prescriptive in detailing processes or steps that should be undertaken. In addition, the particular factors that are pertinent in reaching a sound policy decision will invariably vary from State to State (for example, access to anesthesia services in rural areas). We agree governors should be given the discretion and maximum flexibility to decide with whom they should consult, and this regulation does not prevent governors from consulting with others should they find it necessary.

In addition, we realize States have experience in promulgating laws and soliciting opinion of various types from various professional organizations. For example, in 1997, Oregon passed a Law (SB 412–69th Congress) requiring the State Board of Nursing to adopt scope of practice for CRNAs, and establish procedures for issuing certification of special competency for a CRNA. This law, which allows CRNAs to deliver specified services in hospitals without medical collaboration, and allows CRNAs to deliver specified services in ASCs if no anesthesiologist is available, was a direct result of collaboration and compromise between the Oregon Medical Association, the Oregon Association of Hospitals and Health Systems, the Oregon Association of Nurse Anesthetists, and the Oregon Society of Anesthesiologists. Therefore, we do not agree that CMS should set standards, guidelines, or criteria for a consultation process to be used by any State. We are giving the States flexibility to develop a process that works best for its particular situation and unique needs.

Comment: A few commenters stated that requiring Boards of Medicine's input would place one profession (medicine) in a position to dictate how another profession (nursing) should be regulated. Commenters further argued that requiring Boards of Medicine's input would have obvious ''anti-competitive implications,'' and could encourage behavior that would hinder their ability to practice without physician supervision. Commenters in opposition to the opt-out method stated this is a cumbersome process that, by mandating consultation with the Board of Medicine, allows physicians to ''initiate their brand of grass roots politics.''

Response: CMS is not asking the governor to allow one profession to make judgements regarding the scope of practice of another. As noted above, the governors are using this consultation to gather information that may or may not be used in making a decision regarding the delivery of anesthesia services. This consultation serves as an opportunity for participants on both sides of the issue to have their opinions, issues and concerns heard, first hand, by the individual or designee responsible for making the decisions regarding whether to opt-out of the Federal supervision requirement.

C. State Law Determination

The proposed rule gave the governor the ability to exercise the right of exemption from the physician supervision requirement of CRNAs, if it was in the best interest of that particular State and if it was consistent with State law.

Comment: The majority of comments focused on the interpretation of existing States' scope-of-practice laws. Commenters requested clarification and the promulgation of documented procedures detailing the means by which State law would be determined, and suggested that CMS provide steps and guidance to accomplish this. They argued that a more specific process should be established for determining whether opting-out is consistent with State law. One commenter suggested revising the regulations text to require the governor to attest that the opt-out is consistent ''with all relevant State laws,'' arguing that in most States, several statutory codes or regulations ''issued pursuant thereto'' bear on the issue whether a nurse anesthetist may practice with or without supervision by or in collaboration with a physician and are thus germane to the issue of whether opt-out is consistent with State law.

Response: We recognize there is a difference of opinion of those parties on both sides of this issue, regarding what State law is, but we believe the governors are best suited to make determinations in this area. Anesthesiologists have argued that only one State, New Hampshire, allows CRNAs to practice without physician supervision. Anesthesiologists further argue that the American Association of Nurse Anesthetists (AANA) calculated the number of States permitting independent CRNA practice based solely on nursing regulations and ignored the mandate of the ''medical acts,'' hospital regulations, and controlled-substance laws. Conversely, the AANA argues that 39 states do not have a physician ''supervision'' requirement for CRNAs scope of practice laws or regulations. The AANA further states if one takes into account State hospital licensing laws or regulations, 30 States still do not require physician supervision. They continue by stating if clinical ''direction'' requirements are considered in addition to supervision, 31 States do not have physician supervision or directions requirements for CRNAs in nursing or medical laws or regulations. And last, taking into account State hospital licensing laws or regulations, 20 States still do not require physician supervision or direction requirements.

Objective interpretation of this issue was provided by a 1998 Journal of the American Medical Association (JAMA) article. In this article, Cooper, Henderson, and Dietrich concluded that 18 States permit CRNAs to practice ''independently.'' (Cooper, Richard A., Henderson, Tim, Dietrich, Craig L., ''Roles of Nonphysican Clinicians as Autonomous Providers of Patient Care.'' JAMA. 1998; 270:795–802, at page 797 in Table 2). The ASA challenged the findings of this article, contending its

figures were incorrect. The authors of this article reasserted (in a letter published at page 511 of the February 10, 1999 issue of JAMA), that their findings are correct. The authors stated in their letter that they used data collection from not only the nonphysician clinician organizations, but also the Health Policy Tracking service at the National Conference of State Legislatures and the Internet Web sites of individual States. It was from these sources, they stated ''we have concluded that CRNAs have the authority to practice independent of physician supervision in 18 states.''

Under this final rule, CRNAs would be allowed to practice without physician supervision where State law permits subject to the governor's attestation. Likewise, CRNAs would have to be supervised by a physician where such oversight is required by State law or hospital policy. It would not allow a CRNA to practice outside the scope of authority granted by State law, nor would it prohibit, limit, or restrict in any way the practice of medicine by a physician or anesthesiologist. We emphasize that if State law establishes a more stringent rule on administration of anesthesia, hospitals would be required to comply with State law. In addition, hospitals can always exercise stricter standards than required by State law. The final rule would not require hospitals under any circumstance, to eliminate physician supervision if they deem this appropriate. Again, we believe that the governor is best suited to determine whether an opt-out is consistent with State law.

Comment: Commenters suggested that we strengthen the requirement by mandating a written opinion of a State attorney general to support any opt-out decision, arguing that determination of the issue of ''consistent with State law'' will require examination of the nursing code, medical code, various institutional codes, codes for controlled substances, and reconciliation of the terms of each code to the others. These commenters concluded that this is a task ''normally'' performed by the State attorney general.

Response: States have their own regulatory and administrative structures and rules in place, and we respect the authority of States to meet regional/local needs. State authorities are experienced at regulating the licensing, education, training, and skills of the professionals practicing under their purview, without the burden of prescriptive Federal regulations. The Congress has left this licensure function to States, and Medicare recognizes the scope of practice for which health professionals are licensed by States. Given this, we believe States have the responsibility for clarifying their laws and seeking opinion, if needed, on definition of terms such as collaboration, direction or the allowance of CRNAs to practice without physician supervison. This one exception to Medicare's standards for deferring to States on health professionals licensure matters, does not require further unnecessary burdensome restrictions such as mandatory solicitation of the attorney general's opinion.

Comment: Commenters requested that CMS provide procedural safeguards to ensure that the State governors, in their exercise of their discretion, would observe existing State laws in regards to physician supervision.

Response: This administration strongly believes in deferring to State authority whenever possible. The proposed strategy strikes an appropriate balance between the equally important goals of maintaining patient safety and encouraging state innovation and flexibility, especially in areas where States have historically had a strong role. We are not restricting or limiting the legislative or regulatory process at a State level. If governors feel it is in the best interest of their State to allow CRNAs to practice without supervision, they do have the authority to promulgate laws allowing such practice.

E. Governors' Authority to ''Opt-out''

The proposed rule would give governors the ability to exercise the option of exemption from the requirement of physician supervision of CRNAs.

Comment: A number of commenters who do not support the July 5, 2001 proposed rule remain opposed to the governors' opt-out authority, stating they do not believe safety standards should differ from State to State. These commenters argue that if governors are allowed to opt out, there will be differences and disparities among the various States, resulting 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. Some of these commenters stated that they accepted the idea that this is a compromise between Federal safety-oriented regulations and the protection of States' rights, but acceptable only if accompanied by stringent regulations guiding this process.

Response: This rule establishes a shared commitment to quality care among us, the States, and Medicare providers. The final rule broadens the overall flexibility of States by permitting individuals and authorities closer to patient care delivery to make decisions about the best way to deliver health care services. States 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. 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. 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: Although commenters believe States should not be able to opt-out, it was strongly suggested that CMS strengthen the regulation text and provide stringent provisions, which should include ''procedural safeguards'' to assure that the rules' opt-out conditions are strictly satisfied. Commenters believed this process is flawed and needs to be fine-tuned and clarified in order to be workable in a practical way. Commenters in support of the July 5, 2001 proposed rule, supported the concept of a governor's right to opt-out of the physician supervision requirement, but only under what was described as the ''limiting conditions'' of the proposed rule. Those commenters objecting to the opt-out stated that the decision would be arbitrary, and that governors would succumb to political pressure. Questions were raised such as, ''can a governor opt-out for a single hospital or surgical center, or class of institutions?''

Response: In the proposed rule, we stated the governor was best able to make a determination of need and safety for his/her particular State. Further, we believe a Federal regulation permitting opt-out for particular classes of institutions or particular facilities would be confusing, and therefore we are not creating a cumbersome process of only allowing specific hospitals or classes of institutions on the Federal level. However, this does not prevent the governor from requesting an opt-out on behalf of such facilities at the State level. This regulation does not and should not impede the State's ability to

create laws and/or regulations that fit its needs. Oregon, for example, has a law that allows CRNAs to practice without physician collaboration in hospitals, and requires collaboration with physicians in ASCs, but will allow independent practice in this setting if a physician is not available. We understand that States are unique and have different needs and priorities, and we are giving those closest to that care the ability to make appropriate decisions.

Comment: It was suggested that CMS create uniform criteria for determining whether opting-out is in ''the best interest of the State's citizens.'' Commenters feared that without set criteria, such determinations would be ''whimsical,'' and not based on objective findings of fact. Commenters suggested using criteria such as permitting opt out when it would—

(1) Materially improve patient access to anesthesia services, or when patient access to anesthesia is quantitatively improved, and

(2) Not materially decrease the quality of anesthesia services and patient care in a State, or quality of anesthesia services and patient outcomes are not quantitatively decreased.

Others argued the governors must determine that there is an ''unusual situation'' where physicians may not be available to provide the necessary supervision.

Response: We are not categorizing specific situations or instances by which the governor has the ability to opt out. As mentioned in the proposed rule, the governor is acting in the best interest of his/her State, within the parameters of State law, and with consideration for patient safety.

Comment: Commenters opposed to the opt-out alternative argue that Governors are poorly equipped to review the literature and make scientifically valid conclusions. Some commenters suggested that allowing States to make their own decisions would result in inconsistency among States and that the Federal Government can best make a single decision for the nation, while others stated governors should be allowed to exercise exceptions that are narrowly tailored to address specific State needs and circumstances.

Response: Our fundamental findings have not changed, as we have stated earlier. Our policy surrounding the January 2001 final rule was based on the principle that States traditionally regulate practitioners' scope-of-practice. This final rule judiciously maintains the current physician supervision requirement as sought by some, yet permits States to opt-out of the requirement if desired, a change to the existing requirement that is consistent with the position of those seeking deference to State law and regulation. It is not unusual to find differences in State law. States make decisions based upon their unique needs and specifications.

Comment: Some commenters suggested the need for CMS to develop and implement a specific process relating to the opt-out. Commenters suggested there needs to be a better understanding of the steps a governor must take prior to opting-out. However, these commenters did not believe further prescriptive Federal regulation is necessary, just clarification. For example, commenters questioned if the governor will have to provide a notice for public inspection, and observe a waiting period of up to 60 days after making this determination, arguing that some additional processes should be required, such as a notice in the **Federal Register**, for adequate public input, and to facilitate a transition to opt-out status. Commenters argued that without these requirements, the potential exists for gubernatorial action without the benefit of input by Medicare and Medicaid beneficiaries, providers, and other interested citizens. One commenter cited proposed changes in statewide methods and standards for setting Medicaid payment rates to be used as a precedent, stating that there is precedent for notice and opportunity to comment. Other suggestions were to require a governor to provide appropriate notice to a State's residents prior to submitting a request to opt-out, and to hold at least one public hearing on the matter. In short, commenters wanted the Federal Government to ensure the governor's decision is made in a public forum. They also wished to have an adequate amount of time for facility and providers to prepare. In contrast, a few commenters believed that no further details need to be included in the regulation as it would only increase the paperwork burden for the hospital, and not guarantee improved quality of patient care.

Response: It is not the role of the Federal Government to prescribe how State law and practice decisions are articulated to State residents. We do not want to apply unnecessary multiple standards when the overarching principle is that the governor has the authority to act according to his or her assessment of the needs and safety of the citizens of that particular State. We recognize that States need to establish a realistic workable process to notify their citizens, public and health care providers of change in scope-of-practice. However, we are opposed to incorporating stringent guidelines that could possibly make this a cumbersome, burdensome process. States currently have mechanisms and administrative rules in place for public notification such as hearings, notices, executive orders, statement of needs, notice of periodic review of rules, and notice of proposed rulemaking, that can be applied to this situation.

Comment: If the opt-out process is adopted, the gubernatorial attestation process should be simple, and not involve burdensome administrative requirements or roadblocks.

Response: We agree. The governor's letter to the Administrator of CMS will be accepted on face value, with no independent CMS scrutiny or analysis of the governors' underlying rationale.

Comment: Commenters emphasized this exemption would establish an unusual situation where a Medicare CoP would not apply to all participating hospitals nationwide. Commenters further questioned if this proposal was consistent with the intent of Congress as expressed in Section 1861(e)(9) of the Social Security Act (the Act), stating it would give the governor absolute veto power of existing State laws.

Response: First, surgery and anesthesia services are optional services for hospitals, so anesthesia CoP does not apply to all hospitals, only those that offer these services. Second, 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: Many commenters told us they were adamantly opposed to the proposed standard permitting a withdrawal of the opt-out at any time. Commenters argued the ability of a governor to rescind a previously granted opt-out at any time would leave the State's hospitals, ASCs, CAHs, providers, healthcare workers and patients in constant turmoil and uncertainty. Commenters stated this could perpetually put hospitals in limbo concerning CRNA supervision requirements, and also questioned CMS's ability to validate compliance with such a system. Commenters further argued that other issues need to be considered, such as potential study or monitoring efforts being undermined, or constant pressure from State medical and anesthesiologist societies. It was suggested, that once opt-outs were

granted, the opt-outs stay in place, and that any subsequent action be pursued through the States' existing state legislative/and or regulatory process. Alternatively, it was suggested that once opt-out were granted, it be required to stay in place for at least a year before it could be withdrawn at a governor's request.

Response: We agree that citizens and the health care community should be kept abreast of such changes. As stated earlier, States already have administrative rules in place governing public notification, and we are not imposing prescriptive burdensome guidelines or interfering with State authority in this area. Since this rule permits governors to opt-out of the Federal supervision requirement at any time, we believe governors should be able to rescind the opt-out at their decision.

Comment: One commenter stated their State (Oregon) is seeking a more permanent solution, like the one published in the January 18, 2001 final rule. The commenter stated that the opt-out method of the July 5, 2001 proposed rule would be cumbersome and redundant as the State has a ''CRNA Practice Act'' (which allows hospitals to utilize CRNA services with or without physician supervision, in hospitals), signed into law in 1997, and includes consultation with the Boards of Medicine and Nursing as well as the Hospital Association and other stakeholders.

Response: Oregon and any other States that have such laws should experience decreased burden associated with this final rule. The 1997 Oregon law encompassed some of the same processes outlined in this final rule (for example, consultation with professional organizations, and the ability for CRNAs to practice independently in hospitals, after consideration of patient safety and benefits to its citizens). We applaud the past efforts in Oregon, and believe the State will continue to make prudent decisions regarding the delivery of anesthesia services that are in the best interest of the citizens of the State.

F. Waivers

Comment: Deferring to State law and reverting to the January 18, 2001 final rule would be the wisest course and the best public policy decision. If CMS does not revert back to the January 18, 2001 final rule, then it should provide automatic waivers for all States that do not require physician supervision of CRNA, and consider a scientifically-valid study, or monitoring effort in such States. Commenters stated this is a far better approach than the proposed opt-out/exemption process. Commenters argued this proposed rule politicizes the supervision issue, and makes it much more difficult to produce a pool of States with no Federal supervision requirement that could be studied. Commenters also requested this automatic waiver for those States that remove their supervision requirements subsequent to the group of States initially granted automatic waivers.

Response: There is no evidence to suggest that governors in States with current laws and practices allowing unsupervised CRNA practice would not opt-out of the Federal supervision requirement.

G. Access

Comment: Commenters in support of the proposed rule, stated that rural access should not be considered a valid argument in removing physician supervision, stating this argument does not supercede patient safety, which can only be provided through physician supervision.

Response: We are sensitive to the issue of access of anesthesia services for beneficiaries. This rule will give States the flexibility to improve access in states that consider this an important issue. Regarding patient safety, this final rule is consistent with our efforts to improve the quality of care furnished through Federal programs, while at the same time recognizing States' traditional domain in establishing professional licensure and scope-of-practice laws.

H. Utilization of Anesthesiologist Assistants

Comment: A commenter questioned the increasing utilization of anesthesiologist assistants (AAs), and wanted clarification of a method to study outcomes related to their services. Commenters pointed out that anesthesiologists are beginning to employ AAs who have 2 years or less of post high school training, and question if this decision is based on safety.

Response: This regulation is not meant to change the scope-of-practice of AAs or the manner in which they function, nor does this regulation seek authority to allow AAs to practice without physician supervision. This concern is out of the scope of this regulation.

IV. Provisions of the Final Rule

This final rule implements changes suggested in our July 5, 2001 proposed rule (66 FR 35395) and clarifies several issues concerning the administration of anesthesia about which we solicited comments in the proposed rule. These changes affect the physician supervision requirements for certified registered nurse anesthetists furnishing anesthesia services in hospitals (42 CFR 482.52), critical access hospitals (42 CFR 485.639), and ambulatory surgical centers (42 CFR 416.42) that participate in the Medicare and Medicaid programs. Under this final rule, the current physician supervision requirement will be maintained, unless the governor of a State, in consultation with the State's Boards of Medicine and Nursing, exercises the option of exemption from this requirement, consistent with State law. We believe these changes will improve the quality of care furnished through Federal programs, while recognizing the States' traditional domain in establishing professional licensure and scope-of-practice laws.

V. Collection of Information Requirements

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

VI. Waiver of the 30-Day Delay of Recission Effective Date

In accordance with Section 553(d) of the Administrative Procedure Act (5 U.S.C. Section 553(d)), final rules ordinarily are not effective until at least 30 days after their publication in the **Federal Register**. This 30-day delay in effective date can be waived, however, if an agency finds for good cause that the delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and its reasons in the rule issued.

On July 5, 2001, we proposed changes to the final rule on CRNA practice published on January 18, 2001, which was to become effective November 14, 2001. We find good cause to waive the 30-day delay in the effective date of the provision in this rule rescinding the January 18, 2001 final rule. Failure to waive the delay in effective date would create an anomalous situation in which the provisions of the January 18, 2001 final rule would be in effect for only a few days before being explicitly amended on the effective date of today's final rule. The rescission is an integral operational part of this final rule. A delay in the effective date for the rescission would be impractical to administer because facility guidance and quality monitoring are not designed to accommodate rapid changes in applicable standards. Therefore, we find

that a 30-day delay in the effective date of the rescission is impracticable, unnecessary, and contrary to the public interest.

VII. Regulatory Impact Analysis

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, CAHs, and ASCs to initiate new processes of care, reporting, or to increase the amount of time spent on providing or documenting patient care services. This proposed rule would provide hospitals, CAHs, and ASCs 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 entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having annual receipts of $5 million to $25 million or less annually (65 FR 69432). For purposes of the RFA, all non-profit hospitals, CAHs, and other hospitals with revenues of $25 million or less annually are considered to be small entities. Ambulatory surgical centers with revenues of $7.5 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 603 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 100 beds.

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.

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, that exceeds the inflation-adjusted threshold of $110 million. This rule places no additional costs for implementation on the governments mentioned. It will allow the governors, through a letter to us, to opt-out of the physician supervision requirement of CRNAs and allow the CRNAs to practice independently where State law permits. If a letter to opt-out is submitted, we estimate each State will bear an additional burden of 4 hours for consultation and administrative preparation of the letter. This change is consistent with our policy of respecting State control and oversight of health care professions by deferring to State 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. We have examined this proposed rule and have determined that this rule will not have a negative impact on the rights, rules, and responsibilities of State, local, or tribal governments.

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

List of Subjects

42 CFR Part 416

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

42 CFR Part 482

Grant programs-health, Health facilities, 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, the Centers for Medicare & Medicaid Services withdraws the rule amending 42 CFR chapter IV published in the **Federal Register** on January 18, 2001 (66 FR 4674) and amends 42 chapter IV as follows:

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).

2. In § 416.42, revise paragraph (b), and add a new paragraph (d) to read as follows:

§ 416.42 Condition for coverage—Surgical services.

* * * * *

(b) *Standard: Administration of anesthesia.* Anesthetics must be administered by only—

(1) A qualified anesthesiologist; or

(2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in § 410.69(b) of this chapter, or a supervised trainee in an approved educational program. In those cases in which a non-physician administers the anesthesia, unless exempted in accordance with paragraph (d) of this section, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.

* * * * *

(d) *Standard: State exemption.* (1) An ASC may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (b)(2) of this section, if the State in which the ASC is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision

requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. 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.

2. In § 482.52, revise paragraph (a), and add a new paragraph (c) to read as follows:

§ 482.52 Condition of participation: Anesthesia services.

* * * * *

(a) *Standard: Organization and staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c)of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

* * * * *

(c) Standard: State exemption. (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

1. 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)).

2. In § 485.639, paragraph (c) is revised and new paragraph (e) is added 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.

(1) Anesthesia must be administered by only—

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

* * * * *

(e) Standard: State exemption.

(1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2)The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

(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: October 11, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 19, 2001.

Tommy G. Thompson,

Secretary.

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BILLING CODE 4120–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Modified Base (1% annual chance) Flood Elevations (BFEs) are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified BFEs are indicated on the following table and revise the Flood Insurance Rate Map(s) in effect for each listed community prior to this date.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards