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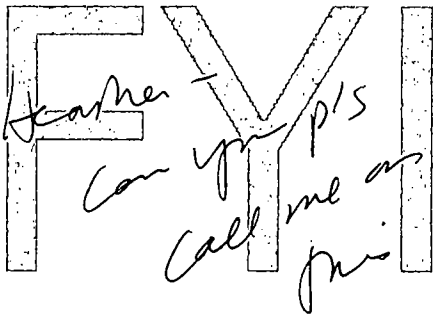
Number of pages, including cover sheet: 2

MESSAGE

Enclosed is a summary of the HCFA supervision issue. We would greatly appreciate any assistance in encouraging the release of this rule for publication before January 20.

FROM MELANNE VERVEER



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Summary of HCFA Supervision Issue

In December, 1997, the Health Care Financing Administration (HCFA) issued a proposed rule as part of its revision of the Medicare Conditions of Participation for Hospitals that would eliminate the current regulation requiring physician supervision of certified registered nurse anesthetists (CRNAs). HCFA had previously issued a draft regulation in 1994 that was circulated and not published as a proposed rule until three years later.

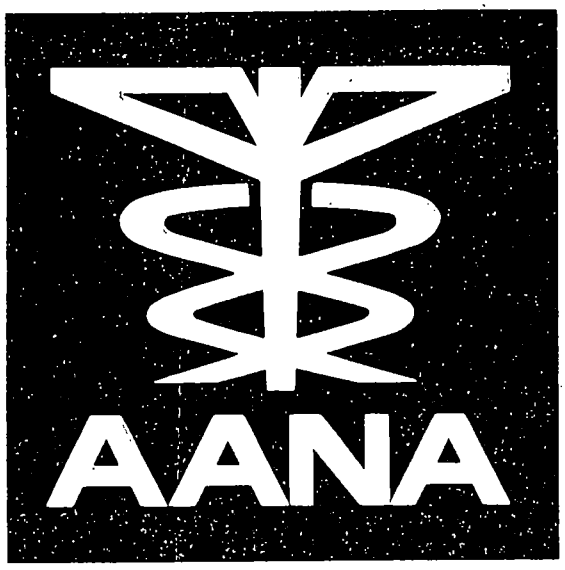
Between January 1, 1998 and present, the American Association of Nurse Anesthetists (AANA) and the American Society of Anesthesiologists (ASA) have been engaged in a legislative battle on Capitol Hill. AANA has sought to encourage Congress to leave the issue alone for HCFA to determine while the ASA has asked Congress to overturn it. Ultimately, Congress did not intervene in 2000.

In March, 2000, former HCFA Administrator Nancy-Ann Min DeParle indicated in a letter to Senator Specter that HCFA intended to move forward and publish the final rule. It was subsequently learned that HHS Secretary Donna Shalala supported the deferral to the states on this issue and the regulation was sent to the Office of Management and Budget (OMB) for final review. It has been pending at OMB since May 31, 2000.

The AANA believes that this regulation should move forward and be published as soon as possible for several reasons:

1. Various Critical Access Hospitals (CAHs) which have previously permitted CRNAs to provide pre and post-anesthesia evaluations without physician supervision may be in danger of losing their CAH status because of the current law.
2. Nurse anesthetists have been dislodged from many employment situations because some anesthesiologists, in their desire to seek those positions for fellow anesthesiologists, have inaccurately informed hospital administrators and/or surgeons that they will be held liable if something goes wrong, simply by virtue of the Medicare supervision requirement. In truth, the surgeon may rely upon either the anesthesiologist or the CRNA for the anesthesia care of the patient and the surgeon is not automatically liable for the errors of the CRNA according to case law.
3. HCFA has previously deferred to the states on the supervision of other healthcare professionals (most recently in November, 1999) and it is fairly standard for states to regulate the scope of practice for health care professionals. If OMB refuses to allow this regulation to move forward, nurse anesthetists will continue to be unfairly singled out for federal regulation and supervision.

We would appreciate any assistance in encouraging OMB to move forward and release this rule for publication prior to the conclusion of the Administration.



American Association of Nurse Anesthetists

PHOTOCOPY
PRESERVATION

AANA
American Association of Nurse Anesthetists

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Certified Registered Nurse Anesthetists (CRNAs) are anesthesia specialists who administer anesthetics to patients undergoing surgical, obstetrical or other operative procedures.

WHAT IS A CERTIFIED REGISTERED NURSE ANESTHETIST?

A certified registered nurse anesthetist is an advanced practice nurse who administers anesthesia. Today, certified registered nurse anesthetists (CRNAs) administer more than 65 percent of the anesthetics given to patients each year for all types of surgical cases. CRNAs are the sole anesthesia providers in 65 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization capabilities. They work in every setting in which anesthesia is delivered, including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers, and the offices of dentists, podiatrists, and plastic surgeons.

ABOUT AANA

- Founded in 1931, the American Association of Nurse Anesthetists (AANA) is the professional association that represents over 27,000 practicing certified registered nurse anesthetists (CRNAs) across the United States.

- The AANA has produced educational and practice standards, implemented a certification process for nurse anesthetists in 1945, and developed an accreditation program for nurse anesthesia education in 1952. The AANA was a leader in forming multidisciplinary councils with public representation in order to fulfill the profession's autonomous credentialing functions. The credentialing processes are broadly recognized by numerous public and private agencies.

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A BRIEF HISTORY OF NURSE ANESTHESIA

- Nurses were the first professional group to provide anesthesia services in the U.S. Established in the late 1800s as the first clinical nursing specialty, nurse anesthesia was developed in response to the growing need surgeons had for specially trained anesthetists. The profession continued developing in the early 1900s through the efforts of Dr. William Mayo and the mother of nurse anesthesia, Alice Magaw, at the facility later known as the Mayo Clinic.

- World War I increased the demand for anesthetists and, as a result, the training of nurses for this field escalated. Existing nurse anesthetists trained both physicians and nurses to provide anesthesia services at home and abroad. The formalization of physician education in the field of anesthesia did not become prevalent until after World War II. Only seven anesthesiology residencies for physicians, of at least one year of specialty training, were in existence at the outbreak of World War II.

- Nurse anesthetists have been the principal anesthesia provider in combat areas in every war in which the United States has been engaged since World War I. In World War II, there were 17 nurse anesthetists to every one physician anesthetist. In Vietnam, the ratio of CRNAs to physician anesthetists was approximately 3:1. During the Panama strike, only CRNAs were sent with the fighting forces.

- Nurse anesthetists have been pioneers in anesthesia for specialty surgery, particularly lung and heart surgery. They were involved in the development of anesthesia equipment for utilizing certain anesthesia techniques.

- CRNAs were the first specialty nursing group to receive direct Medicare Part B reimbursement under the Omnibus Budget Reconciliation Act of 1986.

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NURSE ANESTHETISTS AND PHYSICIAN ANESTHESIOLOGISTS: WHAT IS THE DIFFERENCE?

EDUCATION

- The most substantial difference between CRNAs and anesthesiologists is that prior to anesthesia education, anesthesiologists receive medical education while CRNAs receive nursing education. However, the anesthesia part of the education is very similar for both providers. CRNAs and anesthesiologists are both educated to use the same anesthesia processes in the provision of anesthesia and related services.

- Nurse anesthesia students graduate with a master's degree after completion of a two to three year accredited graduate program in anesthesia, depending upon university requirements. The educational curriculum requires both advanced academic courses and extensive clinical experiences. The student entering a nurse anesthesia program is a licensed professional nurse, has an appropriate baccalaureate degree, and has one or more years of experience in acute or critical care nursing.

- The course of study for an anesthesiologist requires a baccalaureate degree; completion of medical school; and a four-year anesthesiology residency program consisting of one year of a rotating or general medical experience, two years of anesthesia education, and a fourth year of elective experiences related to anesthesiology.

PRACTICE

- The practice of anesthesia is a recognized specialty within both the nursing and medical professions. Both CRNAs and anesthesiologists administer anesthesia for all types of surgical procedures, from the simplest to the most complex, either as single providers or in a "care team setting."

- Some state licensing laws regulating nurse anesthetists require CRNAs to work under the supervision or direction of a physician, such as a surgeon, dentist, podiatrist, or other provider. However, no state licensing statute requires nurse anesthetists to be supervised by an anesthesiologist.

- The principles governing the liability of a surgeon or obstetrician when working with a CRNA are the same as those governing the liability of a surgeon or obstetrician when working with an anesthesiologist. There is no greater liability when one of these providers is working with a CRNA instead of an anesthesiologist. Whether or not a surgeon or obstetrician will be held liable when working with a CRNA depends on the facts of the case, and not on the particular license of the anesthesia provider.

- No studies to date that have addressed anesthesia care outcomes have found that there is a significant difference in patient outcomes based on whether the anesthesia provider is a CRNA or an anesthesiologist.

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5/4 Nurse Anesthetists

Dave Helsel (AANA)

Barbara Woolley

Medicare Part A
- NA are physician supervised

Hosp in rural H

1994 - draft reg - deferring to states
overturning the reg.

1997 proposed rule

29 states don't require supervision

3/9 - informed by HCFA final rule to come out in June

There will be a fight: wider on approps - maybe requiring re study
Medicare reform, prescription drugs

concerned about legislative response

Hospitals w/ them
AMA against, Bob Dole, Gephardt, Downey

analogies - Nurse Practitioners rule finalized 11/99
- defers to states
didn't get same hue + cry

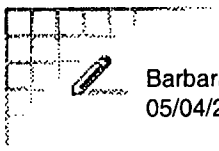
not talking about expand scope practice - want to continue doing what Nurse does

always
H can impose additional regulations
(Major ones by MD's)

Medical Direction

Medical Direction - anesthesiologists can supervise 4 patients at a time right 1/2 fee

H like - gives more flexibility
+ takes away the specter of liability



Barbara D. Woolley
05/04/2000 12:09:43 PM

Record Type: Record

To: Heather H. Howard/OPD/EOP@EOP

cc:
Subject: 3;30 meeting

fyi.
---------- Forwarded by Barbara D. Woolley/WHO/EOP on 05/04/2000 12:09 PM ----------

David Hebert <dhebert@aanadc.com>
03/21/2000 09:40:49 AM

Record Type: Record

To: Barbara D. Woolley/WHO/EOP

cc:
Subject: HCFA Rule on Deferring to States on Physician Supervision of Nurse Anesthetists

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Barbara:

Don't know if you heard the good news. HCFA contacted us that they intend to publish a final rule in June that defers to the states on the issue of physician supervision of nurse anesthetists. We are very happy about this but know we'll have an active year battling in Congress as the anesthesiologists attempt to overturn HCFA's decision either in the appropriations process or through Medicare reform (if there is any). We hope that White House would be willing to deliver the message to the Hill that it would not support overturning HCFA's decision.

Let me know if you have any questions.

Regards,

Dave

David Hebert
Director of Federal Government Affairs
American Association of Nurse Anesthetists
dhebert@aanadc.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

MAR - 8 2000

The Honorable Arlen Specter
United States Senate
Washington, D.C. 20510

Dear Senator Specter:

I wanted to follow-up on our discussion in which you inquired about the status of the certified registered nurse anesthetist (CRNA) supervision issue contained in our December 1997 hospital conditions of participation (CoP) Notice of Proposed Rulemaking (NPRM).

As you know, our proposed rule would change the Federal requirement for physician supervision of CRNAs administering anesthesia. We proposed that CRNAs would practice without physician supervision where State law permits or would be supervised by a physician where such oversight is required by State law. The change proposed was consistent with our policy of respecting State and hospital control and oversight of health care professionals by deferring to State licensing laws to regulate professional practice. In addition, hospitals can always exercise stricter standards than required by State law. We proposed the change because the clinical evidence supports that anesthesia outcomes have improved substantially in recent years such that anesthesia is a relatively safe procedure. In view of this, the existing across-the-board supervision requirement did not seem to be supported by the existing scientific evidence.

We received over 60,000 comments on the proposed rule, including more than 20,000 comments on the CRNA issue. We have spent many months analyzing those comments, and in addition, about 80 Members of Congress have expressed support of the proposed rule, arguing that it is appropriate to leave this matter to State regulation. At the same time, about 100 Members have expressed opposition to the proposed rule on the grounds that it would compromise patient safety.

To complicate matters further, both the FY 1999 and 2000 appropriations bills contained report language concerning this issue. The FY 2000 report indicated: "With regard to physician supervision of anesthesia services under Medicare's Conditions of Participation, if the Secretary determines that there is insufficient current scientific data comparing mortality and adverse outcome rates in the provision of anesthesia service to Medicare patients, the Secretary should conduct a comparative outcome study and report

back to the parties to the agreement. If the Secretary believes that she has sufficient mortality and quality information regarding the provision of anesthesia services by nurse anesthetists and anesthesiologists, then she could make the appropriate regulatory changes to ensure access to quality care for Medicare beneficiaries."

During our conversation, you requested that HCFA make a decision one way or the other and move forward as soon as possible. I understand your concern that we resolve this issue expeditiously, and I am writing to confirm that we expect to separate the CRNA supervision issue from the overall hospital CoPs and move to finalize it ahead of the rest of the hospital conditions regulation. Our goal is to finalize this portion of the hospital CoPs regulation by June 2000.

Sincerely,

Nancy-Ann Min DeParle

Nancy-Ann Min DeParle
Administrator

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 416, 482, 485, and 489

[HCFA-3745-P]

RIN 0938-AG79

Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The revised requirements focus on patient care and the outcomes of that care, reflect a cross-functional view of patient treatment, encourage flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are necessary to reflect advances in patient care delivery and quality assessment practices since the requirements were last revised in 1986. They are also an integral part of the Administration's efforts to achieve broad-based improvements in the quality of care furnished through Federal programs and in the measurement of that care, while at the same time reducing procedural burdens on providers. In addition, in an effort to increase the number of organ donations, we are proposing changes in the interaction between hospitals and organ procurement organizations. The proposed rule also would specify that HCFA may terminate the participation agreement of a hospital, skilled nursing facility, home health agency, or other provider if the provider refuses to allow access to its facilities, or examination of its operations or records, by or on behalf of HCFA, as necessary to verify that it is complying with the Medicare law and regulations and the terms of its provider agreement.

DATES: Comments will be considered if received at the appropriate address, as provided below, no later than 5 p.m. on February 17, 1998.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-3745-P, P.O. Box 7517, Baltimore, MD 21207-0517.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or

Room C5-09-26, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-3745-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

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FOR FURTHER INFORMATION CONTACT: Frank Emerson, (410) 786-4656, Doris Jackson, RN, (410) 786-0095, Rachael Weinstein, RN, (410) 786-6775.

SUPPLEMENTARY INFORMATION:

I. Introduction

As part of the President's and Vice President's regulatory reform initiative, the Health Care Financing Administration (HCFA) is committed to changing current regulations that focus largely on requirements for measuring procedural standards. One of HCFA's key initiatives in Reinventing Government (REGO) is to revise many of its conditions of participation (COPs) to focus on outcomes of care and to eliminate unnecessary procedural requirements. HCFA is working in partnership with the rest of the health care community to institute better, more commonsense ways of operating. On March 10, 1997 we published a proposed rule (62 FR 11004) that includes revisions for COPs for HHAs. Within the coming year, HCFA plans to propose revisions to the COPs for hospitals and end stage renal disease (ESRD) facilities and also to mount additional research in the area of ESRD to provide the basis for future changes.

What these efforts have in common is—

1. Reinventing Government (REGO) Initiative

To meet our REGO commitment, we are focusing on an approach for all sets of COPs that are:

- Transitional toward a patient outcome based system.
- Intended to stimulate improvements in processes, outcomes of care, and patient satisfaction.
- Patient centered.
- Supported by patient outcomes data.
- Interdisciplinary in the approach to care delivery, reflecting the team approach to health care delivery.

The COPs generally adhere to these basic requirements, varying in some degree due to the unique environment and patient case mix of the provider type.

2. Transitional Framework

The transitional framework for each set of COPs—

- Begins shifting the oversight focus toward patient health outcomes and away from burdensome and costly procedural requirements, restructures the traditional COPs along essential conditions centered on patient care, and reflects an interdisciplinary team approach to patient care.
- Prepares the foundation for provider adoption and use of more detailed patient outcome measures developed through private sector experience and research.
- Provides a flexible framework for incorporating better measures as they are developed and tested.

3. Structure

The basic structure of all of the COP follows the Joint Commission on Accreditation of Healthcare Organizations' (JCAHOs) "Agenda for Change." This structure involves reducing the number of conditions; focusing on comprehensive assessment and patient outcomes; and deleting,

transferred to long-term care facilities, who can suffer considerable adverse effects from long-term use of antipsychotic and antianxiety drugs that may have been started in the hospital for very valid reasons but that may no longer be valid after discharge. A study by Garrard (Garrard, Judith, *et al.*, "Evaluation of neuroleptic drug use by nursing home elderly under proposed Medicare and Medicaid regulations," *JAMA*, 265 (1991): 463–467) showed that the rate of use of neuroleptic (antipsychotic) drugs among nursing home admissions was: 16 percent when admitted from hospitals, 18 percent from the community, and 21 percent from other nursing homes. Regulation of the use of these drugs (in the absence of proper differential diagnoses) in nursing homes have been in effect since 1990 (see 42 CFR 483.25), and we have been criticized because similar rules were not imposed on hospital and community practice (Thurston, Ronald G., Letters, *JAMA*, 265 (1991): 2962). We believe this proposed requirement represents a fair way to address this issue, but invite public comment on alternatives for achieving the same objective.

8. Nutritional Services (§ 482.40)

Currently, the food and dietetic services requirements that a hospital must meet are found at § 482.28. These requirements emphasize the organizational aspects of a hospital's food and dietetic services program, including provisions that specify allowable contractual arrangements, employee qualifications, and other process-oriented details.

We are proposing extensive revisions to these provisions under a new nutritional services condition of participation. In keeping with the principles discussed above, the new condition of participation would promote a patient-centered approach to nutrition. Thus, the introductory language for these proposed requirements states explicitly that each patient must receive adequate nutrition, including therapeutic diets or parenteral nutrition if needed.

The proposed condition includes only two standards. The first standard, "Sanitary conditions," requires that food provided to patients be obtained, stored, prepared, distributed and served under sanitary conditions. (Note that the term "food" is intended to include all forms of nutrition, liquid or solid, provided to patients.) Although this requirement is not contained in the current hospital conditions of participation, we believe that it clearly is an underlying necessity for any acceptable nutritional services program. Thus, we are proposing to include it explicitly under the nutritional services condition. The only other standard would require that menus be prepared in advance and meet the nutritional needs of patients based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. We believe the Board's guidelines can appropriately be used here because they represent accepted best practices and are already in widespread use among hospitals.

In developing the proposed requirements, we have attempted to incorporate straightforward statements of a hospital's responsibilities, while eliminating procedural requirements and avoiding unnecessary details of how the hospital should carry out its nutritional services function. We believe that the requirements largely incorporate current best practices in hospital nutrition services, while eliminating several burdensome process requirements that are not central to meeting the patient's dietary needs (such as the requirement under current § 482.28(b)(3) that a current therapeutic diet manual approved by the dietitian and medical staff be readily available to all medical, nursing, and food service personnel.) We considered supplementing the requirements with additional provisions concerning staffing requirements or qualifications. Instead, however, we decided that the staffing requirements set forth under the proposed human resources condition of participation are sufficiently broad to ensure that a hospital has adequate qualified staff to carry out its nutritional services function. Rather than prescribing how a hospital should organize itself to meet its nutritional services responsibilities, we prefer to allow each hospital as much flexibility as possible in this regard, so that it can focus on incorporating its nutritional services program into a cross-cutting approach toward achieving optimal patient outcomes. Finally, as discussed above in section II.B.4 of this preamble, we note that the existing requirement under § 482.28(b)(1) that a therapeutic diet be prescribed by the responsible practitioner would now be encompassed within the hospital's responsibility under proposed § 482.20(b) to ensure that all patient care services be provided in accordance with the orders of qualified practitioners.

9. Surgical and Anesthesia Services (§ 482.45)

The proposed condition on surgical and anesthesia services would replace the existing regulations at § 482.51 (Condition of participation: Surgical services) and § 482.52 (Condition of participation: Anesthesia services). We have decided to address both areas under a single condition in order to simplify the organization of part 482, and to emphasize the close relationship between surgery and anesthesia.

In the new condition, we would delete current process-oriented standards having to do with the organization and staffing of the hospital's surgical and anesthesia departments or services (existing § 482.51(a) and § 482.52(a)), and with hospital policies governing surgical and anesthesia care (existing § 482.51(b) and § 482.52(b)). In particular, we propose to delete the current specific requirements regarding the types of personnel who can serve as scrub nurses or perform circulating duties in the operating room. We also would eliminate current rules on which practitioners can administer anesthesia, and what level of supervision must be provided to them. We also propose to delete current prescriptive requirements specifying the types of equipment that must be maintained in operating suites (existing § 482.51(b)(3)). We believe those requirements should be eliminated in favor of those that focus more directly on outcomes.

In place of the current requirements, we propose two basic rules on staffing. We would require that surgical procedures be performed only by practitioners with appropriate clinical privileges, and that anesthesia be administered only by a licensed practitioner permitted by the State to administer anesthetics.

One effect of our proposed staffing and equipment requirement would be to allow more flexibility to certified registered nurse anesthetists (CRNAs) to practice without oversight by another practitioner. Currently, the anesthesia condition (§ 482.52(a)(4)) requires that a CRNA administer anesthesia only under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed. To allow greater flexibility to hospitals and practitioners and to give deference to State scope of practice law, we propose to delete this supervision requirement and allow the CRNA to function without supervision by another practitioner, where this is in accordance with State law. We emphasize that CRNAs are allowed to practice in this way only where doing so is consistent with State law. If State law establishes a more stringent rule, the hospitals (42 CFR 482.110) would be required to furnish care in a way that is consistent with that rule.

To ensure that our requirements are consistent across the settings in which surgery may be performed, we propose also to eliminate the supervision requirement for CRNAs in ambulatory surgical centers (ASCs) (42 CFR 416.42) and in critical access hospitals (CAHs) (formerly rural primary care hospitals) (RPCHs) (42 CFR 485.639) and allow the CRNA to function without supervision by another practitioner, where this is in accordance with State law. In addition, if State law establishes a more stringent rule, the ambulatory surgical centers (42 CFR 416.40) and critical access hospitals (42 CFR 485.608) would be required to furnish care in a way that is consistent with that rule.

We believe it is critical to the health and safety of surgical patients to have accurate information on each patient's condition before anesthesia is administered and a surgical procedure is undertaken. Therefore, we would require under proposed § 482.45(b) that a comprehensive assessment be performed before surgery (with a modified assessment being permitted in emergency cases) and that a preanesthesia evaluation be done by an individual qualified to administer anesthesia. We also would require that a postanesthesia evaluation for proper recovery be done by an individual qualified to administer anesthesia. We propose to delete the current prescriptive rule under which the postanesthesia evaluation must be done by the same individual who administered the anesthesia.

In the standard on documentation of care, we have included requirements for entry of specified information in the medical record. The information that would be required includes a report of the comprehensive or modified pre-surgical assessment, a properly executed informed consent form, an operative report describing complications, reactions, length of time, techniques, findings, tissues removed or altered, a record of intraoperative anesthesia, and a report of the postanesthesia evaluation. By "properly executed informed consent," we mean only that the patient understands the information the hospital wishes to convey. The pre-surgical assessment and informed consent form would have to be entered in the record before surgery except in emergency cases, while the operative report, intraoperative anesthesia record, and a report of the postanesthesia evaluation would have to be entered in the record promptly following surgery. (The postanesthesia evaluation report combines the current requirements for an inpatient postanesthesia followup report (§ 482.52(b)(3)), and for an outpatient postanesthesia evaluation (§ 482.52(b)(4)) into a single new requirement.) The hospital also would be required to maintain a complete, up-to-date operating room register. We recognize that our proposal for the documentation requirements for the surgical and anesthesia services COP is more extensive and specific than many other requirements in these proposals. However, such documentation is common to current practice and imposes no additional burden to hospitals as these documentation requirements are part of the existing COPs.

10. Emergency Services (§ 482.50)

We propose to delete the existing regulations at § 482.2 (Condition of participation: Provision of emergency services by nonparticipating hospitals), and to add a single new emergency services condition that would replace both current § 482.12(f) (Condition of participation: Governing body; Standard: Emergency services) and current § 482.55 (Condition of participation: Emergency services). We believe § 482.2 need not be retained since the regulations at 42 CFR 424.101 set forth a definition of "hospital" that is used for purposes of payment for services to Medicare patients that are furnished on an emergency basis by a hospital that does not participate in the program. By addressing the two latter areas under a single regulation, we hope to simplify the organization of the regulations and eliminate the need for the user of the regulations to refer to separate sections to review the rules on closely related services. For the reasons explained below, we also are proposing to add a separate standard for hospitals that offer emergency services on less than a full-time basis.

In the standard on hospitals providing full-time emergency services, we have emphasized requirements that most directly affect the safety of patients. These are the requirements regarding the personnel who furnish the services, the appropriateness of the services to patient needs, and the integration of emergency services with those of other hospital departments. Regarding the proposed requirement for sufficient numbers of personnel, we note that some hospitals may choose to meet patient needs by using a comparatively smaller, but more highly trained and skilled staff. In assessing compliance with this requirement, our primary concern will be to determine whether emergency service staffing is adequate to produce good treatment outcomes.

We are proposing the second standard, which is applicable only to hospitals providing part-time emergency services, in order to allow more flexibility to hospitals that find it necessary, because of staffing limitations, low emergency room volumes, or other factors, to limit the times during which emergency services can be offered. Because of the nature of emergency services, it clearly would be desirable to have them available on a 24-hour per day, 7-day per week basis. However, many hospitals, particularly those that are small and are located in remote rural areas, find it difficult to recruit and pay staff to furnish emergency services on this schedule. To avoid a situation in which these hospitals find it necessary to terminate emergency services altogether, we propose that hospitals that are located in rural areas and have fewer than 100 beds may offer emergency services on a part-time basis. We propose to use the definition of "rural area" now set forth in our regulations at 42 CFR 412.62(f)(1)(iii). Under that definition, an area is considered "rural" if it is located outside any Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), and outside specified New England counties.

We emphasize that this flexibility is not intended to foster development of dual standards of care—during its stated hours of operation, a hospital emergency department or service must meet exactly the same standards as full-time departments or services. However, at the times when it chooses not to offer emergency services, the hospital would be required to meet only the standard for hospitals that do not offer emergency care.

Section 1867 of the Act (Examination and Treatment of Emergency Medical Conditions and Women in Labor) imposes certain obligations on Medicare-participating hospitals that have emergency departments. If an individual comes to the hospital's emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide, within the capability of its emergency department, an appropriate medical screening examination and, if necessary, either stabilizing treatment or an appropriate transfer. Section 1867 of the Act does not deal explicitly with the situation of a hospital that opens its emergency department on only a part-time basis. However, it is our policy that a hospital that offers emergency services on a regular, part-time basis is not considered to have an emergency department under section 1867 at the scheduled times when emergency

§ 482.40 Condition of participation: Nutritional services.

The hospital must provide each patient with adequate nutrition, including therapeutic diets or parenteral nutrition if needed.

(a) *Standard: Sanitary conditions.* The hospital must provide food to the patient that is obtained, stored, prepared, distributed and served under sanitary conditions.

(b) *Standard: Menus.* The hospital must prepare menus prepared in advance and meet the nutritional needs of the patients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.

§ 482.45 Condition of participation: Surgical and anesthesia services.

If the hospital provides surgical or anesthesia services, they are provided through the use of qualified staff. The patient receives appropriate pre- and post-procedure evaluations, and all care is accurately documented.

(a) *Standard: Staffing.*

(1) Surgical procedures are performed only by practitioners with appropriate clinical privileges.

(2) Anesthesia is administered only by a licensed practitioner permitted by the State to administer anesthetics.

(b) *Standard: Evaluations.*

(1) A comprehensive assessment of the patient's condition is performed before surgery, except in emergency cases where a modified assessment is acceptable.

(2) A preanesthesia evaluation by an individual qualified to administer anesthesia is performed prior to the administration of anesthesia.

(3) A postanesthesia evaluation for proper anesthesia recovery is performed by an individual qualified to administer anesthesia.

(c) *Standard: Documentation of care.*

(1) The comprehensive or modified presurgical assessment described in paragraph (b)(1) of this section is entered in the patient record before surgery, except in emergency cases, where the assessment may be entered following surgery.

(2) A properly executed informed consent form for the operation is entered in the patient's record by the hospital before surgery, except in emergency cases where the delay needed to obtain consent would place the health or safety of the patient in serious jeopardy.

(3) The hospital maintains a complete, up-to-date operating room register.

(4) The hospital writes or dictates an operative report describing complications, reactions, length of time, techniques, findings, and tissues removed or altered immediately following surgery enters it in the patient's record promptly following surgery.

(5) The hospital maintains an intraoperative anesthesia record enters it in the patient's record promptly following surgery or any other procedures requiring anesthesia.

(6) The hospital writes a report of the results of the postanesthesia evaluation described in paragraph (b)(3) of this section and enters it in the patient's record promptly following completion of the procedure for which anesthesia was required.

§ 482.50 Condition of participation: Emergency services.

The hospital provides, within its capabilities and its stated mission, services appropriate to the needs of persons seeking emergency care. If the hospital provides emergency services on a full-time or part-time basis, it meets the applicable standard in paragraph (a) or paragraph (b) of this section, respectively; if the hospital does not provide any emergency services, it meets the standard in paragraph (c) of this section.

(a) *Standard: Hospitals providing full-time emergency services.* If the hospital provides emergency services on a 24-hour-per-day, 7-day per week basis, the hospital meets the following requirements at all times:

(1) The hospital has sufficient numbers of personnel, including doctors of medicine or osteopathy, other practitioners and registered nurses, to meet patient needs for emergency care.

(2) The services are appropriate to patient needs.

(3) The emergency services provided are integrated with other departments of the hospital.

(b) *Standard: Hospitals providing part-time emergency services.* If the hospital provides emergency services, but not on a 24-hour per day, 7-day per week basis, the hospital meets the following requirements:

(1) The hospital has fewer than 100 beds and is located in a rural area as defined in § 412.62(f)(1)(iii) of this chapter.

(2) The hospital establishes regular hours and days when the emergency services are available, and actually has services available at all of those times.

(3) The hospital notifies local emergency services personnel, law enforcement agencies, physician offices, and other health facilities of when it does and does not offer emergency services, and provides those it has notified with at least 5 calendar days' advance notice of any changes in its emergency services schedule.

(4) The hospital posts its days and hours of operation of emergency services in a conspicuous place where the public most commonly is informed of the hospital's location.

(5) The hospital complies with the requirements of paragraphs (a)(1) through (a)(3) of this section at all times when it does offer emergency services.

(6) The hospital complies with the requirements of paragraph (c) of this section at all times when it does not offer emergency services.

(c) *Standard: Hospitals not providing emergency services.* If the hospital does not provide emergency services, the hospital must provide for appraisal of emergencies, initial treatment, and referral when appropriate.

§ 482.55 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. This process assures that appropriate posthospital services are obtained for each patient, as necessary.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify, at an early stage of hospitalization, all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.*

(1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing posthospital services, including hospice services, and of the availability of those services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for posthospital care are made before discharge, and to avoid unnecessary delays in discharge.

Support HCFA's Decision

Support HCFA's Decision to Defer to the States Regarding Physician Supervision of Nurse Anesthetists

Oppose Any Effort that Would Deny States' Rights

The Health Care Financing Administration (HCFA) has informed the AANA that HCFA expects to issue a final rule that would eliminate the federal requirement for physician supervision of Certified Registered Nurse Anesthetists (CRNAs) in hospitals and ambulatory surgical centers (ASCs) participating in Medicare, and defer to state law. This final rule is targeted to be released in June.

The previous policy of physician supervision restricted the ability of states to determine whether physician supervision of nurse anesthetists was necessary, did not improve the quality of care, and may have inhibited access to anesthesia services in rural areas.

Although this final rule has not yet been issued, Congress needs to show its support for it by simply leaving the rule alone. We anticipate efforts by the anesthesiologists to stop or delay HCFA from promulgating its final rule by either promoting the delaying tactic of a study or other deleterious tactics. We ask you to respect HCFA's decision to defer to state law.

- ***CRNAs Safely Provide Over 65% of the Nation's Anesthesia***

According to the recently released Institute of Medicine report titled "To Err Is Human," anesthesia delivery provides a model for advancement in the safe delivery of health care:

> ***"Anesthesiology has successfully reduced anesthesia mortality rates from two deaths per 10,000 anesthetics administered to one death per 200,000–300,000 anesthetics administered."*** (Pg. 125.)

CRNAs provide 65% of the anesthetics given to patients in the United States on an annual basis.

- ***HCFA Has No Directive from Congress to Further Study This Issue***

The anesthesiologists would like you to believe that anesthesia outcomes need to be further studied; however HCFA is under no such mandate. In fact the report language included in the Conference Report to the Balanced Budget Refinement Act of 1999 discussing the anesthesia issue specifically states:

> ***"If the Secretary believes that she has sufficient mortality and quality information regarding the provision of anesthesia services by nurse anesthetists and anesthesiologists, then she could make the appropriate regulatory changes to ensure access to quality care for Medicare beneficiaries."***

Clearly the Secretary believes that no further study of this issue is necessary.

- ***HCFA Is Removing Supervision Requirements for Other Nurses***

Reinforcing the nurse anesthetist rule, HCFA has now removed certain supervision requirements for nurse practitioners and clinical nurse specialists in their Revisions to the Year 2000 Physician Fee Schedule. (Federal Register 11/2/99: 59415.)

MESSAGE FOR CONGRESS: <u>Support HCFA's decision to defer to the states regarding physician supervision of nurse anesthetists by cosponsoring S. 866/H.R. 804.</u> Oppose any legislative effort that would interfere with states' rights and would delay or stop HCFA from taking action on this final rule, specifically H.R. 632/S. 818.

For additional information please contact David Hebert or Wendy Parker at 202/484-8400.

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Support Managed Care Reform
Support Provider Nondiscrimination Language

Act Now, Not Later

Last year, Congress struggled to pass landmark legislation that makes great strides in protecting patients enrolled in managed care plans. Congress needs to move this managed care reform through conference into law—this year, not next. Act now, not later.

- ***Managed care reform makes sense.*** The Norwood-Dingell component of managed care reform legislation that passed last year was carefully crafted to address the real concerns that have emerged from the recent practices of many HMOs. It contains sensible provisions such as a point-of-service option, and a prohibition of discrimination against providers based on license or certification, and sensible liability reform that protects patients. It does not leave patients out in the cold.

- ***The Norwood-Dingell component is the bipartisan, compromise piece.*** This part of the legislation was carefully negotiated by members from both parties. The result is a bipartisan compromise with a delicate balance that has broad appeal. It won the support of the House by a wide margin. In addition, the Norwood-Dingell bill has the support of 300 patient, consumer, and provider groups.

- ***Norwood-Dingell addresses critical issues for providers and patients.***

    - **Provider Nondiscrimination:** Health plans should be prohibited from engaging in restrictive practices such as "MD-only" policies. Such policies restrict choice and limit marketplace competition, and should be prohibited. Exclusion of a class of providers based solely on their license or certification restricts consumer access to qualified professionals that are licensed and certified by state law. Norwood-Dingell includes this provision.
    - **Accountability:** Unlike the Senate bill, the Norwood-Dingell component offers patients true protection with a process of accountability that is fair to patients and plans. Anything less would allow plans to escape liability through loopholes and exemptions.
    - **Point-of-Service Option:** Any managed care reform legislation must include a point-of-service option that allows patients reasonable access to the provider of choice, regardless of whether or not they are in the network.

MESSAGE FOR CONGRESS: Support a strong patient protection bill that includes provider nondiscrimination language, enforceable accountability provisions, and a point-of-service option.

For additional information please contact David Hebert or Greta Todd at 202/484-8400.

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Support Funding for Nursing Education

Many areas of the country are currently experiencing a severe shortage of nurse anesthetists. There are approximately 83 nurse anesthesia programs across the country, with over 2,000 students. These programs produced approximately 880 graduates who were certified last year, but this rate is not sufficient to provide adequate anesthesia care in some areas of the country. Continued federal funding is vital to produce a stable supply of nurse anesthesia graduates in order to ensure availability of anesthesia services for patients across the country.

There is a shortage of nurse anesthetists all across the country.

- From Alabama to Michigan, and Washington to New York, hospitals and programs are reporting a shortage of nurse anesthetists. It has been reported that as many as 59 percent of institutions are actively recruiting for nurse anesthetists (AANA Administrative Management Committee, 1998).

- The supply of practicing nurse anesthetists into the 21st century will be impacted by an increasing number of retiring practitioners. According to an actuarial study (Revak & Jaffe, 1998), this impact could be softened by maintaining the number of nurse anesthetists graduates at the 1998 level of 975. However, only 881 graduates became certified in 1999, and the number is projected to dip even further in 2000.

The Health Professionals Scholarship Program helps to meet this need.

- Patients in underserved areas depend heavily on the graduates of programs supported by the Health Professionals Scholarship Program, including nurse anesthesia graduates. The Health Professionals Scholarship Program addresses problems of distribution of providers as well as supply, by offering incentives that result in better distribution of health professionals in areas of need.

- Many nurse anesthesia students rely heavily on grant funding from the Health Professionals Scholarship Program (Title VIII of the Public Health Service Act) in order to complete their education. Past funding of this scholarship program has produced significant, measurable results in the effort to increase the number of nurses providing care in rural and underserved areas. Over 75% of nurse anesthetist graduates since 1994 have relied on Title VIII grants. Continued support is crucial.

- The recent reauthorization of the program (The Health Professions Education Partnership Act, passed during the 105th Congress) recognizes the importance of a steady supply of nurse anesthesia students by requiring a minimum investment in nurse anesthesia education.

MESSAGE FOR CONGRESS: Support continued federal funding for all nursing education at least at the level of $50.598 million, to ensure that the required minimum of $2.868 million be set-aside for nurse anesthetists in FY 2001.

For additional information please contact David Hebert or Greta Todd at 202/484-8400.

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