

**Submitter :** Dr. Robb Mothershed  
**Organization :** Dr. Robb Mothershed  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Robb A. Mothershed, DPM

**Submitter :** Dr. Cary Zinkin  
**Organization :** American Podiatric Medical Association  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25th, 2005)

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Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare and Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,  
Cary M. Zinkin, D.P.M.

**Submitter :** Dr. David Secord  
**Organization :** Coastal Bend Foot & Ankle Associates, Inc.  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

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Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,  
David Secord, DPM, FACFAS, FASPD, FAPWCA  
5350 South Staples Street  
Suite 100  
Corpus Christi, TX 78411

**Submitter :** Dr. Richard Odom  
**Organization :** Scott & White Hospital/Clinic  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

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Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Richard D. Odom DPM, CPC  
Scott & White Hospital/Clinic  
Santa Fe Clinic  
600 South 25th Street  
Temple, Texas 76504

**Submitter :** Dr. Roger Beck  
**Organization :** Florida and American Podiatric Medical Association  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

Re: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examination; Proposed Rule(70 Fed. Reg. 15266, March 25, 2005

Dear Dr. McClellan:

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Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&P's). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&P's.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services(CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Roger G. Beck, DPM

**Submitter :** Mrs. Anne Marie Bicha  
**Organization :** American Gastroenterological Association  
**Category :** Health Care Provider/Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3122-P-330-Attach-1.DOC

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**Note:** CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

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**Submitter :** Dr. Richard Eisner  
**Organization :** American Podiatric Medical Association  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Richard S. Eisner, D.P.M., F.A.C.F.A.O.M.  
Past-President, Massachusetts Podiatric Medical Society

**Submitter :** Ms. Joanna Person  
**Organization :** CMS Regional Office  
**Category :** Dietitian/Nutritionist

**Date:** 05/24/2005

**Issue Areas/Comments**

**Issue**

**Authentication of verbal orders**

I find it concerning that the changes will 1) allow a practitioner other than the one who gave an order to verify a telephone order 2) a different anesthesiologist professional will be allowed to evaluate a patient of another professional after administration of an anesthetic.

These changes partially alleviate practitioners of accountability for the work they do. Furthermore, only the practitioner who gives an order knows what their intentions were for the patient, not another practitioner.

The anesthesiology professional most familiar with the patient's medical history and administers or gives the orders for the drugs administered, knows best the expectations for the patient and should be held accountable.

This seems like an opportunity for physicians to see yet more patients when they are already swamped. CMS should balance patient care and profits, and always err on the side of better patient outcomes.

**Submitter :** Ms. Monica Chiasson  
**Organization :** Our Lady of Lourdes RMC  
**Category :** Hospital

**Date:** 05/24/2005

**Issue Areas/Comments**

**Issue**

Timeframe for completion of the medical history and physical examination

Current interpretive guidelines for this regulation indicates History and Physical must be completed or updated "prior to surgery" for inpatient and outpatients. Will that part of the interpretive guidelines remain? Will that be added to the regulation itself?

**Submitter :** Dr. Bradley Haves  
**Organization :** Florida Podiatric Medical Association  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dr. McClellan,

I am a Podiatric Physician, and the current Secretary of the Florida Podiatric Medical Association, and I support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely and Professionally,

Bradley C. Haves DPM  
Secretary, Florida Podiatric Medical Association

**Submitter :** Dr. Maureen Caldwell  
**Organization :** Podiatry Associates Of Victoria PA  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Maureen L. Caldwell, DPM, AACFAS, CWS

**Submitter :** Dr. Andrew Young  
**Organization :** Podiatry Associates Of Victoria PA  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

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Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,  
Andrew J. Young, DPM, AACFAS

**Submitter :** Dr. Albert Burns  
**Organization :** California School of Podiatric Medicine  
**Category :** Other Practitioner

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3122-P-337-Attach-1.DOC

May 23, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
P. O. Box 8010  
Baltimore, MD 21244-8010

**Re: CMS-3122-P**

Comments on Medicare and Medicaid Programs; Hospital Conditions of Participation Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am writing on the behalf of the California School of Podiatric Medicine (CSPM) at Samuel Merritt College to provide comments on the proposed rule that would revise four of the current hospital conditions of participation (CoPs) for approval or continued participation in the Medicare and Medicaid programs. CSPM supports the proposed revision to the medical staff requirement at 482.22(c)(5) to specify that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861® of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians are, by education and training, capable of performing a comprehensive history and physical examination for any of their patients. At CSPM, their education specifically includes four semesters of general medicine courses, a history and physical diagnosis lab course in the students' sophomore year, a medicine rotation on a medical team their junior year, and a medicine rotation on a medical team their senior year. The medicine rotations occur at St. Mary's Medical Center in San Francisco, which has an internal medicine residency program, and they work at the same level as the medical students from Creighton University, who also rotate there. The graduates of CSPM are well prepared for their postgraduate residency programs, where they perform comprehensive history and physical examinations throughout their training, with increasing levels of autonomy.

CSPM is pleased with the proposed revisions to the hospital CoPs involving history and physical examinations and we look forward to them being finalized immediately. If you have any questions concerning our comments, please do not hesitate to contact me.

Sincerely,

Albert E. Burns, DPM  
Academic Dean

Cc: AACPM Board of Directors  
APMA Board of Directors

**Submitter :** Ms. Beth DeLair  
**Organization :** University of Wisconsin Hospital and Clinics  
**Category :** Hospital

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

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**Note:** CMS did not receive an attachment to this document. This may have been due to improper submission by the commenter or it may have been a result of technical problems such as file format or system problems.

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**Submitter :** Dr. Ronald Jensen  
**Organization :** Dr. Ronald Jensen  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

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Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Ronald D. Jensen, DPM

**Submitter :** Dr. Edgar Canada  
**Organization :** California Society of Anesthesiologists  
**Category :** Health Care Professional or Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-3122-P-340-Attach-1.DOC

May 24, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

*Via e-mail*

Re: File Code CMS-3122-P  
Medicare and Medicaid Programs; Hospital Conditions of Participation; Requirements  
for History and Physical Examinations; Authentication of Verbal Orders; Securing  
Medications; and Postanesthesia Evaluations  
(70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

The California Society of Anesthesiologists (CSA) is a state component of the American Society of Anesthesiologists representing over 3,600 anesthesiologists in California. We commend CMS for proposing changes to two provisions of the Hospital Conditions of Participation that have caused confusion and misinterpretation by surveyors and administrators in hospitals: securing medications and postanesthesia evaluations. We urge you to implement the changes as presented in the proposed rule.

#### Securing Medications

In California hospitals in the early 2000s, enforcement of requirements for securing medications was inconsistent and often overly rigid. Administrators of hospitals being surveyed by the state Department of Health Services (DHS) or JCAHO feared citations for noncompliance and would impose unsafe measures that posed threats to patient safety. In order to gain clarity how the security requirements were properly applied in operating rooms, the CSA requested that the DHS specifically address whether anesthesia carts were considered secured when transporting a patient to the post-operative recovery room. In response, the DHS issued a memorandum on medication security stating explicitly that "anesthesia carts and anesthetic machines may remain unlocked during and in between consecutive surgical cases in a given operating room, as long as there are surgical service personnel in the immediate vicinity." This clarification was welcomed by anesthesiologists, administrators and surveyors alike.

There has never been any question that controlled drugs must be under lock. On the other hand, locking up the non-controlled medication on top of or in anesthesia carts between cases in a busy operating room is a threat to patient safety: if the patient suddenly needs a life saving drug on the cart while the anesthesiologist is accompanying him or her to post-anesthesia recovery, delayed access could be lethal.

The CSA is extremely pleased, therefore, with CMS' proposal to revise §462.25(b)(2) to require that "*all drugs and biologicals be kept in a secure area, and locked when appropriate.*" This formulation is consistent with the ASA Position Statement on

Security of Medications in the Operating Room that we were also pleased to see referenced in the notice published in the Federal Register on March 25, 2005.

The Federal Register notice cited several examples of areas that would be deemed secure under the new standard, e.g., private offices and procedure rooms. It did not, however, mention operating suites and anesthesia carts. We request that CMS list operating suites among the examples of secure areas, so there is no confusion between the federal rule and the state of California DHS interpretation of the requirement. Areas restricted to authorized personnel are generally be considered "secure" under the revised standard; CSA recommends, and revised §462.25(b)(2)(iii) would require, that access to operating room suites be strictly limited to authorized persons. We also agree with CMS that if there are medication security problems, the hospital must at that time assess and if appropriate modify its systems and processes.

#### Completion and Documentation of the Postanesthesia Evaluation

The CSA appreciates CMS' response to concerns about the current requirement in §482.52(b)(3) that the practitioner who administers the anesthetic personally write a follow-up report within 48 hours after surgery. The proposed regulation would allow any individual who is qualified to administer anesthesia to complete and document the postanesthesia evaluation.

In making the postanesthesia evaluation standard consistent with the preanesthesia evaluation rule at §482.52(b)(1), CMS has greatly simplified the regulation. This will give anesthesiology departments much needed flexibility to deploy anesthesiologists so as to ensure the highest quality and timeliness of postoperative anesthesia care.

On behalf of our members and their patients who will benefit from ensuring the ready availability of critical anesthesia medications in busy, secure operating rooms and from the ability to schedule anesthesia practitioners to perform postoperative evaluations in a way that is best for patient and practitioner, we thank you for proposing to change the hospital Conditions of Participation regulations. If you have any questions, please do not hesitate to contact us through Barbara Baldwin at 650-345-3020 or [bbaldwin@csahq.org](mailto:bbaldwin@csahq.org).

Sincerely,

Edgar D. Canada, MD  
President  
California Society of Anesthesiologists

**Submitter :**

**Date: 05/24/2005**

**Organization :**

**Category : Physician**

**Issue Areas/Comments**

**GENERAL**

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RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examination; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

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Based on the education, training, and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Richard M. Hofacker, DPM

Submitter : Dr. CHRIS BOWERS  
Organization : Dr. CHRIS BOWERS  
Category : Physician

Date: 05/24/2005

Issue Areas/Comments

GENERAL

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RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

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Thank you for your consideration of these comments.

Sincerely,

CHRIS BOWERS, DPM

**Submitter :** Dr. James Thomas  
**Organization :** Dr. James Thomas  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I appreciate the opportunity to offer comment and state my strong support for the CMS proposed rule change allowing qualified podiatric physicians to perform medical history and physical examinations. The rule change will certainly lead to a more efficient admission process and will inevitably lead to enhanced delivery of safe, high-quality healthcare.

This rule change will also bring Medicare CoPs into alignment with current JCAHO standards, which already allows the performance of admission H&P's in both the hospital and hospital-owned ambulatory settings. As a practitioner of foot and ankle surgery for over 20 years, and now practicing in a large university academic center, I have been forced to deal with this issue on a repetitive basis. This rule change would end decades of confusion and wasted time both for the practitioner and administrator, as well as the patient.

In summary, I would give this proposal my highest support and look forward for the great improvement in patient care that would result.

Sincerely,

James L Thomas, DPM  
Associate Professor  
Department of Surgery  
Division of Orthopaedic Surgery  
University of Alabama at Birmingham  
School of Medicine

**Submitter :** Dr. James DiResta  
**Organization :** Dr. James DiResta  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

I'd like to comment on the proposed Medicare CoP change to finally permit qualified podiatrists the authority to perform the preoperative history & physical exam on their admissions for surgery as previously approved by the JCAHO. This privilege is an inherent right and obligation of all podiatric physicians for the patients they serve.

In asserting this standard of care it finally allows an official change in podiatric physician practice in the hospital setting that is long overdue, is cost effective and more importantly, improves the quality of care that our podiatric patients deserve. As a class it will not merely shift the burden of responsibility to the podiatric physician but more importantly change practice behavior, increase the quality of care provided by podiatrists who unnecessarily have had that hands tied and ultimately improve the quality of care for all our patients.

Drs Paul Batalden and Don Berwick have long taught me that "every system is designed to get the results it gets?". It is this small change in a Medicare CoP that will allow a real change in health care policy that will truly improve upon our health care system.

Best regards,

James J DiResta, DPM, MPH

**Submitter :** Dr. Robert Yoho  
**Organization :** Des Moines University  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

College of Podiatric Medicine and Surgery

May 24, 2005

Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
P. O. Box 8010  
Baltimore, MD 21244-8010

Re: CMS-3122-P  
Comments on Medicare and Medicaid Programs; Hospital Conditions of Participation Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am writing on the behalf of the College of Podiatric Medicine and Surgery at Des Moines University to offer comments on the proposed rule that would revise four of the current hospital conditions of participation (CoPs) for approval or continued participation in the Medicare and Medicaid programs. The College supports the proposed revision to the medical staff requirement at 482.22(c)(5) to specify that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861? of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

The podiatric medical students at Des Moines University are trained to perform history and physical examinations with the osteopathic medical students. This includes the same physical diagnosis course and same standards to successfully complete the course. Training in performing history and physicals involves our nationally recognized Standardized Patient Assessment Lab. Additional training in history taking and performing a physical examination occurs during the student's rotations and continues throughout residency training.

It is our philosophy and the opinion of the podiatric profession that podiatric physicians be trained to perform a comprehensive history and physical examination. If during the history or physical examination process a medical problem is identified it would be the responsibility of the podiatrist to refer this patient on to a physician trained to evaluate and manage such medical conditions.

On behalf of the faculty at the College of Podiatric Medicine and Surgery we strongly support the approval to recognize doctors of podiatric medicine as having the knowledge and skills to perform a patient history and physical examination.

Sincerely,

Robert M. Yoho DPM, MS  
Dean, College of Podiatric Medicine and Surgery  
Des Moines University

Submitter : Dr. Harold Vogler  
 Organization : Dr. Harold Vogler  
 Category : Physician

Date: 05/24/2005

## Issue Areas/Comments

## GENERAL

## GENERAL

Dear Dr. McClellan:

As you know, the issue captioned above has been a persistent problem for podiatric physicians & surgeons for an extended period of time. The Centers for Medicare and Medicaid Services (CMS) proposed rule would revise four of the current hospital conditions of participation (CoPs) for approval or continued participation in the Medicare and Medicaid programs as it relates to this task-admission H&P by podiatric physicians & surgeons. The JCAHO, several years ago, focused their ?clarity statement? on this issue consistent with our licensure, training and scope of practice. Podiatric Foot & Ankle Surgeons perform office based, Surgicenter based and in-patient hospital surgical procedures, including medical management of lower extremity problems. In the State of Florida, this licensure extends to the hip joint. I am aware that there is a comment period before this new rule take force and I am writing to encourage CMS to consolidate this matter and finalize it in order that Doctors of Podiatric Medicine can appropriately perform their admission H&Ps consistent with our licensure, training and skills. It is in the patient and public interest. It makes no sense that we can perform this task in our offices and surgicenters, but not the hospital. The additional burden of having another licensured doctor perform this task adds additional unnecessary expense to the system and the patient and is simply senseless. This has been a political issue for many years by those that would wish to obstruct the advances of podiatric medicine and surgery. However, such considerations are contrary to State and Federal anti-competitive statutes. The standard of care remains quite identical in all these locations.

This comment period closes tomorrow and I wanted my personal position to be known as highly supportive in resolving this long overdue rule change.

The completion of an admission or outpatient medical H&P examination is of great significance to all Doctors of Podiatric Medicine. The H&P examination of patients is considered a standard of care component of clinical practice that was ingrained in our members throughout both their podiatric medicine and surgical residency training. Similar to the practices of their allopathic colleagues, there are occasions when other physicians or specialists are asked to share in patient care. However, to impose unwarranted H&P restrictions on qualified foot and ankle surgeons that prevent them from being allowed to practice within the scope of their training and licensure was unjustified and unfair to the patients and the community that the hospital is there to serve. The performance of an H&P is an inherent axiomatic scope of practice right that every foot and ankle surgeon retains within his licensure.

Therefore, I would like to endorse and support this proposed revision to medical staff requirement to specify that a medical H&P examination must be completed ?by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.? Section 1861(r) of the Social Security Act has long defined ?physician? in Medicare to include doctors of podiatric medicine.

Due to the fact that many foot and ankle surgeons face significant difficulties within their hospital because Medicare CoPs do not conform to this same standard and is, in fact, inconsistent with JCAHO ? such inconsistency is confusing and improper. Additionally, the ?Guidelines for State Podiatric Medical Practice Acts? prepared by the Federation of Podiatric Medical Boards also clearly states at the bottom of the first page that ?H&Ps are included implicitly in the model ?practice authorized? provision below, as they are currently in most state laws.?

Thank you for the opportunity to express my comments on this important matter.

Sincerely,  
 Harold W. Vogler, DPM, FACFAS  
 Complex Foot & Leg Surgery

**Submitter :** Dr. Kevin Myer  
**Organization :** Dr. Kevin Myer  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations: Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Kevin D. Myer, DPM, AACFAS

**Submitter :** Ms. Mary Crews  
**Organization :** North Carolina Baptist Hospital  
**Category :** Hospital

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3122-P-348-Attach-1.DOC

## CMS-3122-P

**Medicare and Medicaid Programs: Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations****Comments on Proposed Revisions to Current Hospital Conditions of Participation:****Issue Identifier: Completion of the Medical History and Physical Examination**

**Comment:** The proposed changes in timeframes for completion of a medical history and physical to no more than 30 days before or 24 hours after an admission are more consistent with other regulatory requirements. A concern is the requirement that hospitals ensure an updated medical record entry, documenting an examination for any changes in the patient's current condition, be completed within 24 hours after admission. How completely documented must a physical examination be in order to document a change in a patient's condition? For instance, will a statement signed by the physician that "no change" has occurred in the patient's condition be satisfactory? For instance, a patient is admitted for elective knee surgery but breaks his arm between the time the medical history and physical examination is completed and admission. Can the change in condition be documentation of the broken arm alone or must another complete physical examination be reported? To provide safe patient care, but also be less burdensome to those who perform history and physicals, would it not be more appropriate to require a medical record entry documenting a re-examination appropriate to the patient and their condition?

The change to expand those who may complete a history and physical to include qualified individuals who have been granted privileges by the medical staff in accordance with State law is a good change and also provides more consistency between regulatory agencies.

**Issue Identifier: Authentication of Verbal Orders**

**Comment:** The proposed 5-year temporary revision allowing another practitioner who is responsible for the care of the patient to authenticate orders, including verbal orders, within 48 hours even if the orders did not originate with him or her does provide hospitals with flexibility while maintaining an appropriate level of accountability. A concern is that this revision to the authentication requirement may be temporary. With frequent rotations of large groups, particularly in academic medical centers, allowing a responsible practitioner to authenticate orders permanently will be more efficient than only allowing the prescribing practitioner. For instance if the prescribing practitioner goes on vacation and leaves an unsigned order, even if health information technology advances enough to reach him or her, the prescribing practitioner would not want their vacation interrupted to sign an order that has already been executed. Understanding there will be a reevaluation of this temporary revision prior to the conclusion of the 5-year period, we strongly urge making this proposed temporary revision into a permanent authentication requirement of the hospital CoPs.

**Issue Identifier: Securing Medications**

**Comment:** After reviewing the proposed rule related to medication security, we have no concerns with our ability to comply with this proposed rule. In fact, the proposed rule will afford us greater flexibility if deemed appropriate, as our current systems and processes related to medication storage and control are more stringent than the proposed.

**Issue Identifier: Completion of the Postanesthesia Evaluation**

**Comment:** We support the proposed requirement to allow any individual qualified to administer anesthesia to complete and document the postanesthesia evaluation for inpatients versus the current requirement that requires the individual who administers the anesthesia to write the follow-up report.

**Submitter :** Dr. David Schofield  
**Organization :** American Podiatric Medical Association  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

May 24, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

Via electronic submission

RE: CMS-3122-P

Comments on Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA) originally submitted comments to the Centers for Medicare & Medicaid Services (CMS) on April 7th on the provision of the proposed rule that would revise the requirement for completion of a history and physical (H&P) examination. The APMA remains supportive of the proposed revision to the medical staff requirement at ? 482.22(c)(5) to specify that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Since submitting our original letter, we have become aware of other comments submitted that suggest limiting H&P privileges to a doctor of podiatric medicine who has completed an accredited podiatric residency program for patients admitted for podiatric surgery. We do not support this limitation and believe it is inappropriate. Based on the didactic content and clinical training experiences provided to podiatric medical students, we believe that individuals with a doctorate in podiatric medicine are fully qualified for the performance of histories and physicals for their hospital patients.

Additionally, we believe that the suggested limitation is inconsistent with the original intent of the proposed rule. We support the CMS decision to eliminate the current proscriptive standards in favor of more discretionary and outcome-oriented standards and we oppose any attempt to alter the proposed language to impose new restrictions on podiatric physicians.

We appreciate the opportunity to offer these additional comments.

Sincerely,

David M. Schofield, DPM  
President Elect  
American Podiatric Medical Association

**Submitter :** Dr. J. Brian Warne  
**Organization :** Dr. J. Brian Warne  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

**Submitter :** Dr. Michael Maves  
**Organization :** American Medical Association  
**Category :** Health Care Professional or Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-3122-P-351-Attach-1.PDF

# American Medical Association

Physicians dedicated to the health of America



**Michael D. Maves, MD, MBA**  
Executive Vice President, CEO

515 North State Street  
Chicago, Illinois 60610

312 464-5000  
312 464-4184 Fax

May 24, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

**RE: [CMS-3122-P] Medicare and Medicaid Programs; Hospital Conditions  
Of Participation: Requirements for History and Physical Examinations;  
Authentication of Verbal Orders; Securing Medications; and Postanesthesia  
Evaluations**

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the Centers for Medicare and Medicaid Services' (CMS) willingness to address a number of the AMA's previous concerns relating to the above referenced proposed rule. The AMA is pleased to offer the following additional comments in response to proposed rule.

**Requirements for History and Physical Examinations - § 482.22**

The AMA supports the proposed rule to expand the current requirement for completion of a medical history and physical examination from no more than seven days before admission to within thirty days before admission as long as the hospital ensures documentation of the patient's current condition in the medical record within 24 hours after admission.

However, **the AMA does not support** the expansion of the rule to allow "*other qualified individual[s]* who [have] been granted these privileges by the medical staff in accordance with State law" (emphasis added).

AMA policy H-215.995 states the following with respect to hospital admission histories and physicals:

Our AMA believes that the best interests of hospitalized patients are served when admission history and physical exams are performed

by a physician, recognizing that *portions* of the histories and physical exams may be delegated by the physician to others whose credentials are accepted by the medical staff (emphasis added).

Additionally, based on AMA policy H-230.989 concerning the granting of staff and clinical privileges in hospitals and other health care facilities, the AMA believes:

(1) the best interests of patients should be the predominant consideration;

(2) the accordance and delineation of privileges should be determined on an individual basis, commensurate with an applicant's education, training, experience, and demonstrated current competence. In implementing these criteria, each facility should formulate and apply reasonable, nondiscriminatory standards for the evaluation of an applicant's credentials, free of anti-competitive intent or purpose;

(3) differences among health care practitioners in their clinical privileges are acceptable to the extent that each has a scientific basis. However, the same standards of performance should be applied to limited practitioners who offer the kinds of services that can be performed by limited licensed health care practitioners or physicians; and

(4) *health care facilities that grant privileges to limited licensed practitioners should provide that patients admitted by limited licensed practitioners undergo a prompt medical evaluation by a qualified physician; that patients admitted for inpatient care have a history taken and a comprehensive physical examination performed by a physician who has such privileges; and that each patient's general medical condition is the responsibility of a qualified physician member of the medical staff* (emphasis added).

#### **Authentication of Verbal Orders - § 482.24**

The proposed rule allowing “the prescribing practitioner or another practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to write orders by hospital policy in accordance with State law” for the next five years is a positive change. In addition, while the AMA would still prefer to allow “hospitals and their medical staffs to establish their own policies on authentication of verbal orders” (see AMA policy D-225.988), the AMA appreciates that the current 48 hour rule for verification of verbal orders would be applied, under the proposed rule, to only those states that do not currently have a timeframe in place for the verification of such orders.

**Securing Medications - § 482.25**

The AMA is pleased with the proposed changes to this section that would provide hospitals with the flexibility to store non-controlled drugs and biologicals in a “secured area, and locked when appropriate.” We further recommend that the term “secured area” include in-use operating suites and anesthesia carts. We agree with CMS that if there are medication security problems, the hospitals must assess, and if appropriate modify, their systems and processes. Removing the current restrictions on where medications may be stored will ultimately improve the treatment of patients by allowing the administration of important medications to them in a timely manner.

**Postanesthesia Evaluations - § 482.52**

The AMA appreciates that the proposed changes offered by CMS to this section would allow postanesthesia evaluations to be completed and documented by any individual qualified to administer anesthesia under these regulations. This change, which has been a priority of the AMA and American Society of Anesthesiologists (ASA), would, according to ASA, “give hospitals and anesthesiology departments much needed flexibility to deploy anesthesiologists, anesthesiologist assistants and nurse anesthetists so as to ensure the highest quality and timeliness of postoperative anesthesia care.”

Again, the AMA appreciates the opportunity to comment on this important proposed rule. Please feel free to contact me or our Washington, DC office if you have any questions.

Sincerely,



Michael D. Maves, MD, MBA

**Submitter :** Dr. Gary Stein  
**Organization :** American Society of Health-System Pharmacists  
**Category :** Health Care Professional or Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-3122-P-352-Attach-1.DOC

May 24, 2005

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
P.O. Box 8010  
Baltimore, MD 21244-1850



American Society of  
Health-System Pharmacists\*

7272 Wisconsin Avenue  
Bethesda, Maryland 20814  
301-657-3000  
Fax: 301-652-8278  
www.ashp.org

**Re: CMS-3122-P, Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations**

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) March 25, 2005, proposed rule that would revise four of the current hospital conditions of participation (COPs) for approval or continued participation in the Medicare and Medicaid programs. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

CMS proposes changing the COP requirements related to: Completion of a history and physical examination in the medical staff and the medical record services COPs; authentication of verbal orders in the nursing service and the medical record services COPs; securing medications in the pharmaceutical services COP; and completion of the postanesthesia evaluation in the anesthesia services COP.

ASHP believes that, for the most part, the revisions proposed by CMS better reflect current health care practice than the existing regulations. Specifically, we have comments on the following standards:

*Medical History*

CMS proposes to change the standards in §482.22(c)(5) and 482.24(c)(2)(i)(A) to require that a patient's medical history and physical examination be completed no more than 30 days before or 24 hours after admission, rather than 7 days before or 48 hours after admission as required in the current COPs. ASHP supports these changes as an appropriate standard of care.

*Verbal Orders*

CMS proposes to revise 42 CFR 482.23(c)(2)(i) to state that "If verbal orders are used, they are to be used infrequently."

ASHP has recommended, in our “Guidelines on Preventing Medication Errors in Hospitals” ([http://www.ashp.org/bestpractices/MedMis/MedMis\\_Gdl\\_Hosp.pdf](http://www.ashp.org/bestpractices/MedMis/MedMis_Gdl_Hosp.pdf)) the following in regard to verbal orders:

Verbal drug or prescription orders (that is, orders that are orally communicated) should be reserved only for those situations in which it is impossible or impractical for the prescriber to write the order or enter it in the computer. The prescriber should dictate verbal orders slowly, clearly, and articulately to avoid confusion. . . . The order should be read back to the prescriber by the recipient (i.e., the nurse or pharmacist, according to institutional policies). When read back, the drug name should be spelled to the prescriber and, when directions are repeated, no abbreviations should be used. . . . A written copy of the verbal order should be placed in the patient’s medical record and later confirmed by the prescriber in accordance with applicable state regulations and hospital policies.

ASHP believes that the proposed rule would be benefitted by adding the detail in the above recommendation on verbal orders

#### *Securing Medications*

ASHP supports the revisions of the standard in §482.25(b)(2) requiring drugs and biologicals to “be kept in a secure area, and locked when appropriate,” and that “only authorized personnel may have access to locked areas.” This is in keeping with policy in ASHP’s “Technical Assistance Bulletin on Hospital Drug Distribution and Control” ([http://www.ashp.org/bestpractices/drugdistribution/Distrib\\_TAB\\_Hosp.pdf](http://www.ashp.org/bestpractices/drugdistribution/Distrib_TAB_Hosp.pdf)), which states: “Storage is an important aspect of the total drug control system. . . . Storage areas must be secure; fixtures and equipment used to store drugs should be constructed so that drugs are accessible only to designated and authorized personnel.”

#### *Postanesthesia Evaluation*

The revised standard in 482.52(b)(3) states that “With respect to inpatients, a postanesthesia evaluation must be completed and documented by an individual qualified to administer anesthesia as specified in paragraph (a) of this section within 48 hours after surgery.” ASHP believes that many patient-related anesthesia issues can be best handled by pharmacists. Our “Guidelines on Surgery and Anesthesiology Pharmaceutical Services” ([http://www.ashp.org/bestpractices/MedTherapy/Specific\\_Gdl\\_Surg.pdf](http://www.ashp.org/bestpractices/MedTherapy/Specific_Gdl_Surg.pdf)) states:

The pharmacist should take a leadership role in the performance of medication-use evaluations by establishing criteria, collecting data, analyzing the data, making recommendations, and performing follow-up. Data collection is often more easily accomplished prospectively or concurrently by coordination with surgery and anesthesiology staff. High-cost or high-use medications are good starting places for medication-use evaluations in the OR. Medication-use

evaluations are especially useful for assessing compliance with established guidelines.

ASHP believes that CMS should add pharmacists as hospital personnel qualified to assist in completing postanesthesia evaluations under this standard.

ASHP appreciates the opportunity to present comments on this important patient care issue. For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at [gstein@ashp.org](mailto:gstein@ashp.org)

Sincerely,

A handwritten signature in black ink, appearing to read "Gary C. Stein". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Gary C. Stein, Ph.D.  
Director, Federal Regulatory Affairs

**Submitter :** Dr. Eugene Sinclair  
**Organization :** American Society of Anesthesiologists  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attached Letter

CMS-3122-P-353-Attach-1.DOC



**AMERICAN SOCIETY  
OF ANESTHESIOLOGISTS**

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Office of Governmental Affairs

1101 Vermont Avenue, N.W., Suite 606 • Washington, DC 20005  
(202) 289-2222 • Fax (202) 371-0384 • mail@ASAwash.org

May 24, 2005

Mark B. McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

*Via e-mail*

Re: **File Code CMS-3122-P**

Medicare and Medicaid Programs; Hospital Conditions of Participation; Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations  
(70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

The American Society of Anesthesiologists (ASA) would like to commend CMS for proposing to change two provisions of the Hospital Conditions of Participation that have been of much concern to our members: securing medications and postanesthesia evaluations. We urge you to finalize the changes as you have proposed them.

**Securing Medications**

The requirement that carts containing anesthesia medications be locked whenever they are not directly monitored by an individual with legal access to the medications, even within a secure operating room suite, was never published until the State Operations Manual was revised in May, 2004. Nevertheless, numerous hospital surveyors have followed this interpretation and have warned or cited institutions for noncompliance. At least one state, California, took the interpretation so seriously that its Department of Health Services issued a memorandum on medication security stating explicitly that "anesthesia carts and anesthetic machines may remain unlocked during and in between consecutive surgical cases in a given operating room, as long as there are surgical service personnel in the immediate vicinity." This statement is a paraphrase of ASA policy and would follow the CMS proposed position.

American Society of Anesthesiologists  
Comments on 70 Fed. Reg. 15266, March 25, 2005

There has never been any question that controlled drugs must be under lock. Locking up the non-controlled medication on top of or in anesthesia carts between cases in a busy operating room, on the other hand, is a threat to patient safety: if the patient suddenly needs a life saving drug on the cart while the anesthesiologist is accompanying him or her to post-anesthesia recovery, delayed access could be lethal. Accounts of broken locks, forgotten combinations or security codes and other failures or shortcomings of the equipment used to lock up the anesthesia medications are not rare. Moreover, the cost to hospitals of purchasing or leasing and maintaining special locking devices or systems is very substantial – and has not been shown to prevent any contamination or diversion of the anesthesia drugs, which appear not to have been problems in the first place.

ASA is extremely pleased, therefore, with CMS' proposal to revise § 462.25(b)(2) to require that ***“all drugs and biologicals be kept in a secure area, and locked when appropriate.”*** This formulation is consistent with the ASA Position Statement on Security of Medications in the Operating Room that we were also pleased to see referenced in the notice published in the Federal Register on March 25, 2005.

The Federal Register notice cited several examples of areas that would be deemed secure under the new standard, e.g., private offices and procedure rooms. It did not, however, mention operating suites and anesthesia carts. Because a paragraph in the Interpretive Guidelines on § 462.25(b)(2) specifically provides that if an anesthesia cart, nursing or other “cart containing drugs or biologicals is in use and unlocked, someone with legal access to the drugs and biologicals in the cart must be close by and directly monitoring the cart,” we would ask that CMS list operating suites among the examples of secure areas, or otherwise make absolutely unequivocal that the proposed rule does not require direct monitoring of an unlocked anesthesia cart in an operating suite that is in use. Areas restricted to authorized personnel would generally be considered “secure” under the revised standard; ASA recommends, and revised §462.25(b)(2)(iii) would require, that access to operating room suites be strictly limited to authorized persons. We also agree with CMS that if there are medication security problems, the hospital must at that time assess and if appropriate modify its systems and processes.

#### Completion and Documentation of the Postanesthesia Evaluation

ASA appreciates CMS' response to our concerns about the current requirement in §482.52(b)(3) that the practitioner who performs the anesthetic personally write a follow-up report within 48 hours after surgery. The proposed regulation would allow any individual who is qualified to administer anesthesia to complete and document the postanesthesia evaluation. This is a change that ASA has been seeking for some time, as have individual anesthesiologists and the American Medical Association (AMA).

American Society of Anesthesiologists  
Comments on 70 Fed. Reg. 15266, March 25, 2005

In making the postanesthesia evaluation standard a mirror image of the preanesthesia evaluation rule at §482.52(b)(1), CMS has greatly simplified the regulation. This will give hospitals and anesthesiology departments much needed flexibility to deploy anesthesiologists, anesthesiologist assistants and nurse anesthetists so as to ensure the highest quality and timeliness of postoperative anesthesia care.

On behalf of our many members and their patients who will benefit from ensuring the ready availability of critical anesthesia medications in busy, secure operating rooms and from the ability to schedule anesthesia practitioners to perform postoperative evaluations in a way that is best for patient and practitioner, we thank you for proposing to change the hospital Conditions of Participation regulations. If you have any questions, please do not hesitate to contact us through Karin Bierstein, JD, MPH at (202) 289-2222 or [k.bierstein@asawash.org](mailto:k.bierstein@asawash.org).

Sincerely,

A handwritten signature in cursive script that reads "Eugene Sinclair".

Eugene P. Sinclair, MD  
President

**Submitter :** Dr. Walter Strash  
**Organization :** APMA  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Walter W. Strash, DPM, FACFAS  
Diplomat, American Board of Podiatric Surgery  
Board Certified in Foot Surgery  
Board Certified in Reconstructive Rearfoot/Ankle Surgery

**Submitter :** Dr. Thomas Burghardt  
**Organization :** Dr. Thomas Burghardt  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

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Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Thomas Burghardt, DPM

Submitter : Dr. LINDA ALEXANDER

Date: 05/24/2005

Organization : FPMA

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861 (r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&P's). Upon graduation from a podiatric medical school, individuals are full qualified to perform H&P's.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Linda Alexander, DPM

**Submitter :**

**Date:** 05/24/2005

**Organization :**

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

GENERAL

Brandon L. Tullis, DPM, AACFAS  
3612 Dale Road, Modesto, CA 95355  
(209) 544-6088

May 24, 2005

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and surgeon and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,  
Brandon L. Tullis, DPM, AACFAS

**Submitter :** Mr. Glenn Hackbarth  
**Organization :** Medicare Payment Advisory Commission  
**Category :** Federal Government

**Date:** 05/24/2005

**Issue Areas/Comments**

GENERAL

GENERAL

see attachment

CMS-3122-P-358-Attach-1.PDF



601 New Jersey Avenue, N.W. • Suite 9000  
 Washington, DC 20001  
 202-220-3700 • Fax: 202-220-3759  
 www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman  
 Robert D. Reischauer, Ph.D., Vice Chairman  
 Mark E. Miller, Ph.D., Executive Director

May 24, 2005

Mark McClellan, Administrator  
 Centers for Medicare and Medicaid Services  
 Department of Health and Human Services  
 Attn: CMS-3122-P  
 P.O. Box 8010  
 Baltimore, MD 21244-8010

Re: File Code - CMS - 3122 - P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Secretary of Health and Human Services' proposed rule entitled *Medicare and Medicaid Programs; Hospital Conditions of Participation; Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations*, 70 Fed. Reg. 15266 (March 25, 2005). This rule addresses a critical component of the medical record: patients' medical history and physical examination. We are interested in this proposed rule because:

- two of the proposed changes to the conditions of participation could improve the quality of the history and physical, and,
- the Secretary should consider using this rule to require hospitals to identify which secondary diagnoses were present on admission on their claims forms, as we recommended in our March 2005 Report to Congress.

First, the proposed rule would allow a history and physical examination that was performed up to 30 days prior to admission to become part of the hospitals' medical record. We support this change because it may allow hospitals to use the history and physical performed by a patient's regular doctor more often than is possible under the current regulation (which currently restricts hospitals to using a prior history and physical that is seven or fewer days old at the time of the patient's admission). A patient's regular doctor may be able to incorporate knowledge of the patient's long-term health that might not be available to the intake personnel of the hospital. When patients' critical information follows them from one setting to another—from their regular doctor's office to the inpatient hospital—it can enhance the continuity and quality of patient care.

Previously, the regulations allowed hospitals up to 48 hours after admission to complete a history and physical; if a patient had a history and physical that had been taken within the

seven days prior to the admission, then no update of that information was required. The proposed rule would change the requirement so that “when a medical history and physical examination is completed within the 30 days before admission,” the hospital must “ensure that an updated medical record entry documenting an examination for any changes in the patient’s current condition is completed [and] documented in the patient’s medical record” within 24 hours of his or her admission to the hospital. We support this change because requiring an update of a previously-conducted history and physical or conducting a new one within 24 hours helps to differentiate between conditions that developed while the patient was in the hospital from those that were present before admission.

However, the final rule needs to clarify the meaning of “documentation.” The rule’s reference to “documentation” could refer either to indicating only that such an examination took place *or* could refer to recording the results of the examination, e.g. the patient’s new condition. The final rule should clarify that if a patient’s condition has changed since the history and physical was taken—whether previous conditions have been resolved or whether new conditions have manifested—the hospital is required to document patients’ current conditions in sufficient detail to represent the patient’s condition upon admission.

Finally, we believe that the proposed rule is also an opportunity for the Secretary to implement a recommendation from our March 2005 Report to improve the utility of hospital claims data for measuring clinical effectiveness and patient safety. The Commission recommended that CMS should require hospitals to report information about patients’ condition upon admission on the hospital claim submitted for payment. The proposed rule makes important improvements to the quality of the information regarding patients’ condition on admission, but it stops short of requiring the information on the standard claim form.

Adding this information to the claim would make important data available for a far wider range of applications than simply requiring the information in patients’ medical records. Reporting patients’ conditions upon admission could allow CMS, hospital quality improvement personnel, researchers, and others to improve hospital quality measures. More information about patient’s conditions upon admission could greatly enhance measures of patient safety and improve the risk adjustment of clinical effectiveness measures. For example, it would enable a quality measure to distinguish between a patient population that has a high rate of infections when they enter hospitals from a population that may be fairly uncomplicated but frequently acquires infections during their hospital stay.

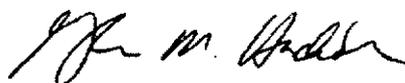
Practical models for changing the hospital claim form are available. A group of clinicians and medical coders have worked together in New York State to draw upon the years of experience in the State of California (where coding patients’ condition upon admission is already required) to

develop a new template for a single, standardized instruction for coders to record this information. CMS could consider the coding guidance and claim forms from either or both of these states. Adding this information to the claim stream would require training coders and making a small adjustment to the hospital claim. However, this change is unlikely to occur if hospitals are not required to do so.

MedPAC appreciates this opportunity to comment on this proposed rule. The Commission values the willingness of CMS staff to provide relevant data and to consult with us concerning technical policy issues.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director at (202) 220-3700.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth". The signature is fluid and cursive, with the first name being the most prominent.

Glenn M. Hackbarth  
Chairman

GMH/sc/w

Submitter : Dr. Clarence Clayton  
Organization : Dr. Clarence Clayton  
Category : Physician

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations: Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and I support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after obtaining an undergraduate degree. As a part of their educational experience, they receive didactic and clinical training in the performance of histories and physicals,(H&Ps). Upon graduation from podiatric medical school, individuals are fully qualified to perform H & Ps, as would any other medical school graduate. Both types of doctors further refine their skills in this area during their residency training as well.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H & P requirement is appropriate. I urge the Centers for Medicare and Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of my comments.

Sincerely,

Clarence G. Clayton, III, D.P.M., F.A.C.F.A.S.  
Diplomate in Foot Surgery, American Bd. of Podiatric Surgery  
Diplomate in Podiatric Orthopedics, Am. Bd.of Podiatric Orthopedics & Primary Podiatric Medicine

**Submitter :** Mr. Michael Davis  
**Organization :** Pennsylvania Podiatric Medical Association  
**Category :** Other Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am the executive director of the Pennsylvania Podiatric Medical Association, an Association that accounts as its members over 80% for the licensed podiatrists in the Commonwealth. Our Association through its board supports the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Micahel Q. Davis  
Executive Director  
Pennsylvania Podiatric Medical Association  
757 Poplar Church Road  
Camp Hill, PA 17011

(717) 763 7665

**Submitter :** Mr. Richard Bloch  
**Organization :** Maryland Podiatric Medical Association  
**Category :** Health Care Professional or Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am Executive Director of the Maryland Podiatric Medical Association, which represents 270 podiatric physicians in Maryland. I am writing on behalf of our members to support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and, as part of the educational experience, receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps). Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, we believe that the proposed change to the H&P requirement is appropriate and we urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,  
Maryland Podiatric Medical Association  
Richard Bloch  
Executive Director

**Submitter :** Dr. Jon Hultman  
**Organization :** California Podiatric Medical Association  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

Dear Dr. McClellan:

I am a podiatric physician and support the proposed revision to the Medicare Conditions of Participation (CoPs) for Hospitals, which specifies that a medical history and physical examination must be completed for each patient by a physician (as defined in section 1861(r) of the Act) or other qualified individual who has been granted these privileges by the medical staff in accordance with State law.

Podiatric physicians attend four years of podiatric medical school after college and a minimum of two years of hospital based, post-graduate residency training. Podiatric physicians receive training in the classroom and in clinical settings in the performance of histories and physicals (H&Ps) as part of the podiatric medical school and post-graduate educational experience. Upon graduation from a podiatric medical school, individuals are fully qualified to perform H&Ps.

Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

Jon A. Hultman, DPM

**Submitter :** Jonathan Morse  
**Organization :** American Physical Therapy Association  
**Category :** Health Care Professional or Association

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-3122-P-363-Attach-1.DOC

May 24, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
P.O. Box 8011  
Baltimore, MD 21244-8011

Dear Administrator McClellan:

Thank you for the opportunity to comment on the Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations published in the Federal Register on March 25, 2005. The purpose of this document is to submit comments on behalf of the American Physical Therapy Association (APTA) in response to the Proposed Rule. The APTA is a national organization representing over 67,000 physical therapists, physical therapist assistants, and students of physical therapy. Many of APTA's members provide services to Medicare beneficiaries in inpatient and outpatient hospital settings. The proposed rule pertaining to authentication of verbal orders has a significant impact on these providers.

Specifically, the proposed rule would require that if there is no existing State law that designates a specific timeframe for the authentication for verbal orders, then the verbal orders would need to be authenticated within 48 hours. CMS is proposing this change because the current regulations require authentication "promptly" which is vague and subject to interpretation by hospitals if no timeframe exists within applicable State law. It is our understanding that the Hospital Conditions of Participation apply to all patients, both inpatient and outpatient, if the services provided are billed under the hospital's provider number. APTA is concerned that this 48-hour requirement is overly burdensome and restrictive in outpatient hospital physical therapy settings where there is less contact and less supervision by the attending physician.

Physical therapy services are unique under the Social Security Act, as Section 1861(p) includes provisions for hospital outpatient physical therapy services and does not require physical therapy to be billed incident to a physician's services. In a hospital outpatient setting, there is no requirement for a physician to be onsite to directly supervise physical therapy services provided by physical therapists. The Act permits physical therapists to function more independently than other practitioners in outpatient hospital departments. Therefore, the 48-hour authentication requirement is an unreasonable restriction on outpatient physical therapy practices, as physical therapists often do not necessarily have contact with the physician within 48 hours.

APTA strongly recommends that CMS exempt physical therapists from the 48-hour requirement for authenticating verbal orders for outpatient physical therapy services furnished by hospitals. We also believe that maintaining the current language requiring

prompt authentication will continue to protect the health and safety of patients. Currently, physical therapists working in hospital outpatient settings begin treatment on a verbal order from the physician. The verbal order is written down and sent back to the physician. If a State does not require written authentication within a specific timeframe, physical therapists abide by the present Federal requirement and will promptly seek written authentication. However, many States do not have prescribed authentication timeframes, and a 48-hour window is often impractical as the physician may not be onsite and has little contact with the physical therapist. For example, if the verbal order comes in on a Friday, the physician may not be available until the following Monday to authenticate the order, which is outside the 48-hour timeframe.

The American Physical Therapy Association would be pleased to work with CMS concerning any questions or additional information APTA can provide on the verbal orders authentication issue. Please contact Jonathan Morse at [JonathanMorse@apta.org](mailto:JonathanMorse@apta.org) or at (703) 706-8547 if you have further questions.

Sincerely,

Dave Mason  
Director of Government Affairs  
American Physical Therapy Association

**Submitter :** Mr. Donald E. Koenig  
**Organization :** Catholic Healthcare Partners  
**Category :** Hospital

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

Dear Mr. McClellan:

On behalf of Catholic Healthcare Partners and our 35 acute care affiliated hospitals within four states, we appreciate the opportunity to comment on the CMS proposed changes to the Medicare Conditions of Participation (CoP) regarding history and physical examinations (H/P), authentication of verbal orders, securing medications, and post-anesthesia evaluations. We appreciate CMS openness to listen to the concerns of providers, to seek ways to streamline burdensome regulations and to clarify policy and procedures that are fundamental to hospital internal operations. However, we are concerned about some aspects of the proposed changes that could result in an unintended shift of liability to the hospital away from the physician / non-physician practitioner who performed the service and potential conflicts with other CMS policy provisions regarding rendering of services. Specifically we wish to comment regarding the following proposed Conditions of Participation changes:

- 1) Clarifying the applicability of the proposed H/P changes to inpatient admissions only, or to specified additional patient statuses
- 2) Clarifying time-frames for ?updated notes? in view of conflicting language in other sections of the Conditions of Participation regulations
- 3) Clarifying whether ?performance?, ?documentation? and ?authentication? on an H/P must be performed by the same individual
- 4) Aligning physician/practitioner incentives to ensure timely completion of accurate H/Ps
- 5) Maintaining requirements for ordering/prescribing physicians/practitioners to authenticate their verbal orders
- 6) Specifying a reasonable time-frame for authentication of verbal orders to occur
- 7) Clarifying whether conscious sedation is subject to the anesthesia Conditions of Participation standard

Attached you will find our specific comments and recommendations on several topics contained within the proposed rule.

Catholic Healthcare Partners appreciates the opportunity to submit comments for your consideration. If your staff has any questions about these comments, please feel free to contact me at 513-639-2833 or Cheryl Rice, Corporate Compliance, Coding and Reimbursement Analyst at 513-639-0116.

/s/ Donald E. Koenig, Jr.  
Vice President, Corporate Responsibility & Assistant General Counsel

See Attachment  
clr

CMS-3122-P-364-Attach-1.DOC

**Submitter :** Dr. John Parent  
**Organization :** Dr. John Parent  
**Category :** Physician

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

RE: CMS-3122-P

Hospital Conditions of Participation: Requirements for History and Physical Examinations; Proposed Rule (70 Fed. Reg. 15266, March 25, 2005)

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Based on the education, training and experience of podiatric physicians, I believe that the proposed change to the H&P requirement is appropriate and I urge the Centers for Medicare & Medicaid Services (CMS) to finalize it without delay.

Thank you for your consideration of these comments.

Sincerely,

John A. Parent, DPM

**Submitter :** Ms. Ellen Rathfon  
**Organization :** American Academy of Physician Assistants  
**Category :** Physician Assistant

**Date:** 05/24/2005

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment concerning postanesthesia evaluation

CMS-3122-P-366-Attach-1.DOC



## American Academy of Physician Assistants

950 North Washington Street ■ Alexandria, VA 22314-1552 ■ 703/836-2272 Fax 703/684-1924

Attachment to #366

May 24, 2005

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3122-P  
PO Box 8010  
Baltimore, MD 21244-8010

File Code: CMS-3122-P

The American Academy of Physician Assistants (AAPA), representing the more than 55,000 practicing physician assistants (PAs) nationwide, would like to take this opportunity to comment on the proposed rule, *Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications, and Postanesthesia Evaluations*, published in the March 25, 2005, **Federal Register**.

We support the intent of the revisions proposed in this rule – to reflect more accurately current practice and to relieve undue burdens on providers and hospitals. In particular, we believe the revisions to the requirements for admission histories and physicals and to the discretion allowed for securing medications will provide flexibility to better meet patient needs.

**We appreciate the idea of broadening the standard for who can perform the postanesthesia evaluation but believe the proposed language does not go far enough.** Section 482.52(b)(3) should be broadened to allow physician delegation to a qualified provider to the extent permitted by state law. This would allow anesthesiologists to delegate the postanesthesia evaluation and report to qualified physician assistants whom they supervise. **The proposed language at §482.52(b)(3) and the parallel language regarding the preanesthesia reports at §482.52(b)(1) unnecessarily limit the ability of physicians to delegate appropriately to qualified PAs.**

Just as a matter of context, we would also note that the Conditions of Participation, at §482.12 “Conditions of Participation: Governing Body,” confer upon MDs and DOs a broad delegatory authority. Section 482.12(c)(1)(i) states, “Every Medicare patient is under the care of: (i) A doctor of medicine or osteopathy. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State’s regulatory mechanism.)”

Unfortunately, when rules such as the COPs confer both a broad authority – as found at §482.12(c)(1)(i) – and a more narrowly defined one – as in this case at §482.52(b)(3) and §482.52(b)(1) – often it is not clear which provision is meant to prevail. We believe adding language at §482.52(b)(3) and §482.52(b)(1) acknowledging physician delegatory authority would provide clarity that would benefit institutions and the patients they serve.

**In general, we believe that much of the COP language around anesthesia, analgesia, and sedation is outdated and should be addressed comprehensively.** The AAPA sees two primary problems with how the Conditions of Participation currently address anesthesia. First, there is no distinction in the regulations between “general anesthesia” and all the gradations of

anesthesia/sedation/analgesia on the spectrum between unarousable unconsciousness and minimal sedation to relieve anxiety. Second, the exclusive list of providers found at §482.52(a)(1) through §482.52(a)(5) is too restrictive. We would agree that while the administration of **general** anesthesia perhaps should be limited to those categories of providers, physician assistants commonly administer other types and levels of procedural anesthesia/sedation/analgesia.

The AAPA is represented on the task force convened by the Joint Commission to look at these types of anesthesia issues in its standards. I plan to follow up with CMS staff on these anesthesia-related questions shortly and thank you for this opportunity to lay the groundwork for future discussions.

Sincerely,

A handwritten signature in black ink that reads "Ellen Rathfon". The signature is written in a cursive, flowing style.

Ellen Rathfon  
Director, Professional Affairs