

Submitter : Dr. Craig Friedman
Organization : Maryland Podiatric Medical Association
Category : Physician

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

05/24/2005

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 practicing in Baltimore, Maryland, and I strongly 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,

Craig S. Friedman, D.P.M.

Immediate Past President

Maryland Podiatric Medical Association

Submitter : Ms. Ginny Jewell
Organization : Indiana Podiatric Medical Association
Category : Health Care Professional or Association

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

INDIANA PODIATRIC MEDICAL ASSOCIATION
201 N. ILLINOIS STREET, SUITE 1910
INDIANAPOLIS, INDIANA 46204
317-237-3569 FAX 317-237-35.67
E-mail: inpma@tcon.net

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 an Executive Director 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.

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Thank you for your consideration of these comments.

Sincerely,

Ginny Jewell
Executive Director

Submitter : Karen Gallagher
Organization : St. Mary's Healthcare Center
Category : Physical Therapist

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

TO: CMS

FROM: Karen Gallagher, PT
Director Rehabilitation Services
May 24, 2005

RE: CMS-3122-P

I am a physical therapist and the Director of Rehabilitation Services at a hospital in Pierre, SD. I am submitting comments regarding the proposed rule published in the March 25, 2005 Federal Register.

Our Rehabilitation Services Department provides physical, occupational and speech therapy and cardiac rehabilitation services to both inpatient as well as outpatients. The proposed rule to require a physician's signature within 48 hours will be problematic in the outpatient setting. For inpatients this is not a concern as the physicians are in the facility on a daily basis.

Getting an order physically to a physician and back to the clinic within 48 hours would be very staff time intensive, as we would likely need to physically carry the order sheet to the local clinics to get the signature. Furthermore, physicians that are out of town would present a problem as well.

I ask that this rule be limited to inpatients to prevent the difficulties and restrictions providing in care in the outpatient setting.

Thank you for your consideration.

Submitter : Mrs. Barbara Haller
Organization : Illinois Hospital Association
Category : Health Care Provider/Association

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3122-P-370-Attach-1.DOC

CMS-3122-P-370-Attach-2.DOC

May 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3122-P

Electronic Submission

Ladies and Gentlemen:

On behalf of its nearly 200 member hospitals and health systems, the Illinois Hospital Association presents the following comments on the proposed rule amending the Hospital Conditions of Participation appearing in 70 FR 15266 et seq.

Completion of the History and Physical Examination (Section 482.22 (c) (5). The change in the required time period for the completion of history and physical examinations (from no more than 7 days before or 48 hours after admission, to within 30 days before admission or 24 hours after admission) will be helpful to hospitals. For example, this change will allow more time for patients of specialists to be referred to their primary physicians for pre-admission evaluation, and for test results to be received by the hospital.

Authentication of Verbal Orders (482.23 (c) (2). This change is problematic in that there are discrepancies between the proposed rule and the current Interpretive Guidelines, that raise the question of whether hospitals, which have recently effected policy and procedural changes to comply with the new Interpretive Guidelines will now be required to make further changes in order to comply with new rules. Furthermore, given the temporary exception to one specific authentication requirement, will hospitals need to make still further changes, upon termination of the exemption period?

A. Interpretive Guidelines

The Interpretive Guidelines of 5-21-04 require that when telephone or verbal orders must be used, the prescribing practitioner must review and authenticate them as soon as possible. A covering physician may co-sign the verbal order of the ordering physician, but it is not to be made a common practice. A physician assistant or nurse practitioner may NOT co-sign a physician's verbal order or otherwise authenticate a medical record entry for the physician who gave the verbal order. "As soon as possible" would be the earlier of the following: the next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record; the prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and hospital policy; or within 48 hours of when the order was given.

June 29, 2005

Page 2

Under the Proposed Rule, changes would be made to the provisions regarding persons who may co-sign a verbal order, and the time frame in which the co-signing must be accomplished.

B. Proposed Rule Change

(1) to 482.23 (c) (2)

Authentication of orders for drugs and biologicals. Except for flu and pneumonia vaccines, orders for drugs and biologicals must be documented and signed by a practitioner who is responsible for the care of the patient and authorized to write orders by hospital policy in accordance with State law.

This broader provision will be helpful to hospitals.

(2) to 482.24 (c) (1) (ii)

Authentication of medical record entries. The rule proposes a temporary exception (5yrs) to the requirement of authentication only by the prescribing practitioner:

All patient record entries must be dated, timed, and authenticated promptly by 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, even if the order did not originate with him or her.

{Section 482.12 (c) provides:

(1) 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.)

The flexibility represented in these changes is welcome; however, CMS should clarify whether a Physician Assistant or Nurse Practitioner who has prescriptive authority under State law is allowed to co-sign a physician's order under the proposed rules.

(3) to 482.24 (c) (1) (iii)

Change to timeframe for authentication. The proposed rule provides:

June 29, 2005

Page 3

All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific time frame for authentication of verbal orders, then verbal orders must be authenticated within 48 hours.

States such as Illinois, with laws that do not provide a specific time frame, will have to amend their law through a statutory or regulatory amendment process, which takes time. In the meantime, hospitals will have to make changes to comply with the new 48 hour rule, and then change again to the time frame designated in their new State rule. The constant changing of procedures is confusing to staff, and presents an unnecessarily burdensome challenge to hospitals.

Thank you for the opportunity to comment on the proposed rulemaking. Please feel free to contact me if you have any questions, or need further information.

Sincerely,

Barbara Haller
Health Policy Analyst
Illinois Hospital Association
630.276.5474

June 29, 2005
Page 4

May 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3122-P

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June 29, 2005

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June 29, 2005

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Thank you for the opportunity to comment on the proposed rulemaking. Please feel free to contact me if you have any questions, or need further information.

Sincerely,

Barbara Haller
Health Policy Analyst
Illinois Hospital Association
630.276.5474

June 29, 2005
Page 4

Submitter : Mr. Spencer Grover

Date: 05/24/2005

Organization : Indiana Hospital

Category : Hospital

Issue Areas/Comments

Issue

Timeframe for authentication of verbal orders

If a requirement that if verbal orders are repeated and verified, and are deemed acceptable by the professional who is responsible for ordering, providing, or evaluating the services furnished, then the verbal order need not be authenticated until the close of the medical record. If the verbal order is not repeated and verified, then it should be authenticated within 48 hours.

Timeframe for completion of the medical history and physical examination

Dictation usually indicates the time dictated, transcribed, and signed. Will you now require that we indicate the time the unsigned H&P was physically placed in the medical record, or does the signature of a responsible practitioner serve as the time stamp?

Authentication of verbal orders

Once a verbal order has been reduced to writing, the licensed health professional or person responsible for ordering, providing, or evaluating the services furnished or by a responsible individual as designated in the hospital and medical staff policies performs the service requested. By repeating the verbal order and verifying that it is written correctly, patient safety and reduction of errors is more greatly enhanced than by an authentication within 48 hours, after the service has been provided once or many times.

Indiana law requires repetition and verification of verbal orders if the physician does not want to authenticate within 48 hours. This is a better approach to preventing errors.

Completion of the medical history and physical examination

Please continue to allow delegation of all or part of the physical examination and medical history to other practitioners. In addition, confirm that the completed H&P could be authenticated by another practitioner responsible for the care of the patient. This is especially important when the H&P are dictated, but the author cannot authenticate between the time the H&P is physically placed on the medical record and the end of the 24 hours following admission.

Nursing services (482.23)

Our polling of physicians and nursing staff show that the use of verbal orders is a common practice. It is certainly not infrequent. The answers vary by physician specialty and location. In rural areas, it can be 100% of the orders received at night and at other times when the patient's condition warrants and the physician is not physically available or capable of secure electronic communication.

To state that verbal orders are to be used infrequently should be tested more with practicing physicians of all specialties in rural and urban settings. We thought this unenforceable relic of a rule would be revised to reflect the better communication standards that have evolved between physicians and those qualified to accept verbal orders. The teamwork that has been developed, the exercise of independent judgement and the capability in protocols not to accept a verbal order that you question or are unsure of are improved safeguards. The ability to repeat the order and verify what was heard as a standard operating procedure, to clarify, and to question as a team member makes the use of verbal orders much safer.

The Indiana Department of Health did a comprehensive study with the Indiana Hospital & Health Association, malpractice attorneys and insurance companies, health care professionals, and risk managers. We found no examples of prescribing practitioners denying that they gave a verbal order after the verbal order was carried out when the order was repeated back to them. After a one year study, it became law in Indiana. Repetition and verification is now standard practice and has reduced errors, increased communication and patient safety. Verbal order Repeat and Verify has the potential to prevent the error in the first place, not discover it in 48 hours.

Submitter : Mr. John Doherty
Organization : MeritCare Health System
Category : Health Care Professional or Association

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3122-P-372-Attach-1.PDF

May 24, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS – 3122 – P
PO Box 8010
Baltimore MD 21244-8010

RE: Proposed Medicare Conditions of Participation for Hospitals

To Whom It May Concern:

I am writing on behalf of MeritCare Health System, a not-for-profit integrated health system located in Fargo, North Dakota. MeritCare serves patients located throughout eastern North Dakota, northwestern Minnesota and northeastern South Dakota. MeritCare has two hospitals located in Fargo, North Dakota.

Our concern is with the proposed Medicare Conditions of Participation for Hospitals, Section II. (A)(2) Authentication of Verbal Orders. A major concern is with the non-compliance of "verbal orders" (telephone and oral) today - and our measurement is against the expectation of 30 days.

While the proposed changes would allow any provider to sign for another that is caring for the patient, legally I doubt that this practice would be held in high regard with the provider community as they are more often than not acting autonomously. We have multiple care providers, as do many other organizations, with teaching services and residents covering off-shifts, hence the utilization of telephone orders that are received. However, the provider may never see the patient in person. The shorter length of stay also adds to the complexity of maintaining a signed hard-copy chart.

All of the above provides examples of why a limit of 48 hours would make extremely difficult, while adding to our already high non-compliance rate.

If you have any questions regarding this matter, please feel free to contact myself at 701.234.6960 or Susan Bosak, Public Affairs Officer at susan.bosak@meritcare.com or 701.234.6332.

Thank you for your time concerning this matter.

Sincerely,

John Doherty
COO

Submitter : Ms. Temple Sellers
Organization : Georgia Hospital Association
Category : Hospital

Date: 05/24/2005

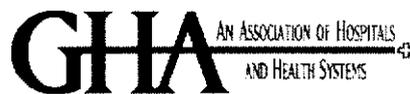
Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-3122-P-373-Attach-1.DOC



1675 Terrell Mill Road • Marietta, Georgia 30067 • (770) 249-4500 • FAX (770) 955-5801 • www.gha.org

May 24, 2005

To: Centers for Medical and Medicaid Services

Re: Comments on Proposed Rule Change to Hospitals Conditions of Participation:
Requirements for History and Physical Examination; Authentication of Verbal Orders;
Securing Medications; and Post-Anesthesia Evaluations
File Code: CMS-3122-P

On behalf of the Georgia Hospital Association (GHA) and our nearly 180 hospitals and health systems, I would like to thank the Centers for Medicare and Medicaid Services (CMS) for this opportunity to provide comments on the proposed rule revising certain hospital conditions of participation (CoPs) for participation in the Medicare and Medicaid programs. GHA appreciates CMS' attempt to revise the CoPs to bring them more in line with current medical practice and to reduce unnecessary administrative burdens for hospitals. While GHA supports a number of the specific proposed changes, we have concerns regarding others. We are also concerned regarding the interplay between these proposed rule and the new CoP interpretive guidelines issued last year. These concerns are discussed more fully below.

- Condition of Participation: Medical Staff Section 482.22(c)(5) – GHA supports the proposed change regarding the time frame for completion of the medical history and physical examination. This rule brings the CoP requirements in line with the JCAHO Standards and with current practice.
- Condition of Participation: Nursing Services Section 482.23 – GHA has no comment regarding the proposed rule. However, as discussed more fully below, GHA is very concerned about the current interpretive guidelines related to this 482.23(c)(2)(ii) and urges CMS to halt implementation of these guidelines until this new CoP is finalized.
- Condition of Participation: Medical Records Services §482.24(c) – ~~§482.24(c)(1)~~ provides as follows: “All entries must be **legible and complete**, and must be **authenticated and dated** promptly by the person (identified by name and discipline) who is responsible for ordering, providing or evaluating the service furnished.” CMS proposes to add a requirement that all entries must, in addition, be **timed**. Currently, neither JCAHO Standards nor Georgia's State Licensure Regulations require all medical record entries be timed. The interpretive guidelines pertaining to §482.24(c)(1) have never required the timing of all entries in the medical record until late last year when CMS issued its new interpretive guidelines. This change is one of many problems created by the new guidelines and is part of an ongoing discussion between CMS and the American Hospital Association. As a result of these discussions,

CMS has agreed to schedule open forums in the near future to discuss these issues with the hospital community. Hospitals around the country are very hopeful that these meetings will result in significant changes to the interpretive guidelines and many hospitals have delayed implementing some of the more burdensome requirements until these issues are fully explored and resolved. GHA is concerned that CMS has proposed to revise this CoP to require the timing of every entry in the medical record before these forums take place because this change would require significant changes to current documentation practices within hospitals.

Currently health care providers time only those medical record entries that require timing for clinical reasons. For example, there are clinical reasons to include in the record the time blood is drawn from a patient for lab work. However, there is no clinical need to time basic progress notes. In addition, in order to increase efficiency and improve quality during the current nursing shortages, many hospitals have developed flow sheets with check boxes. Nurses check appropriate boxes as they provide patient care services. Flow sheets both remind nurses what tasks need to be provided to patients and reduce their paperwork burden. This proposed rule would significantly reduce the effectiveness of flow sheets. Nurses would have to stop what they are doing and look at their watches every single time they check a box, even where there is no clinical reason for them to do so.

Far from reducing unnecessary administrative burdens, this requirement to time every single entry in a medical record without respect to whether there is any clinical need to do so actually creates a very significant new administrative burden for nurses and other hospital personnel. If the purpose for this change is to protect patients, CMS could accomplish this goal without creating an unnecessary burden by revising the rule or the guidelines to require instead that hospitals determine which entries should be timed for quality reasons. GHA urges CMS to remove the requirement in this proposed rule and in the new interpretive guidelines which require the timing of all entries in medical records.

§482.24(c)(1)(i) – CMS proposes to include in this rule a 5 year exception to the requirement that all orders, including verbal orders, must be authenticated by the prescribing practitioner. During these 5 years, CMS proposes to authorize a practitioner other than the prescribing practitioner to authenticate orders, as long as that practitioner is responsible for the care of the patient and is authorized to write orders by hospital policy in accordance with state law. However, at the end of the 5-year time period, this exception will automatically terminate, and hospitals will automatically be required to ensure verbal orders are authenticated only by the prescribing practitioner. The preamble explains this limited time exception anticipates that within the next 5 years the advancement of health information technology will facilitate authentication by the prescribing practitioner.

While GHA shares the current administration's interest in implementing electronic health records, it is highly unlikely that all hospitals in Georgia will be able to afford to implement health information technology fully within the next 5 years. For this reason, instead of including this 5 year exception in the rule, GHA urges CMS to authorize the authentication of verbal orders by practitioners who meet the specified criteria without

any time limitation. CMS can then assess after 5 years whether the implementation of health information technology has occurred and revise the rule at that time if appropriate. GHA is concerned that to do otherwise will result in an undue administrative burden 5 years following implementation of the rule for those hospitals that have been unable to implement health information technology.

§482.24(c)(1)(ii) - GHA strongly supports the proposal to require authentication of verbal orders within the time frame established by state law. Over the course of the last several years, many states, including Georgia, have extended the time frame for the authentication of verbal orders in recognition that a shorter time frame is costly, unworkable and of questionable value. This proposed rule is consistent with that trend. However, GHA is very concerned that the new interpretive guidelines relating to the time frame for the authentication of verbal orders.

The current Nursing Services CoP provides “When telephone or verbal orders must be used, they must be signed or initialed by the prescribing practitioner as soon as possible.” The new interpretive guidelines related to this provision states:

- With respect to verbal orders, 482.23 (c)(2) (i), provides that the ordering practitioner must date and time the order at the time he or she signs the order and 482.23 (c) (2) (iii) requires the prescribing practitioner to sign the verbal order **the earlier** of the following:
 - The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record,
 - The prescribing practitioner signs or initials the verbal order within time frames consistent with Federal and State law or regulation and hospital policy, or
 - Within 48 hours of when the order was given.

This time frame is significantly shorter than the current practice in Georgia as authorized under state licensure regulations. In 2002 Georgia extended the timeframe for authentication from the old “48 hour rule” to “up to 30 days after the patient’s discharge” where the hospital implements a “repeat and verify” process. This change followed a lengthy debate over the effectiveness of the 48 hour rule and a careful consideration by the Georgia Department of Human Resources (DHR) of its associated costs and benefits.

DHR was unable to identify any study to support the theory that the 48 hour rule has any significant impact on preventing patient harm. Verbal/telephone orders are usually carried out upon receipt. If an error occurs, the 48 hour time frame would not prevent the error. At best, the rule may allow a physician to identify an error which has already occurred, sooner, rather than later. DHR concluded that any benefit of the 48 hour timeframe was outweighed by the considerable costs of compliance.

Perhaps the most significant cost is that of nursing staff time. The burden of complying with this rule rests primarily on the shoulders of nurses. There is currently a nationwide

nursing shortage and one of the contributing factors is the amount of time nurses are expected to spend doing things other than caring for patients. This is particularly true in hospitals, which are more heavily regulated than many other patient care settings. Many hospital nurses are retiring early or leaving the hospitals for other less demanding patient care settings.

To comply with old 48 hour rule in Georgia, nurses often reviewed every patient record and tagged the orders that needed to be signed. At the end of the day they would go back through the chart to see if the order had been signed. They also verbally reminded physicians to sign their orders. This process will become even more burdensome and time consuming for nurses if the new guidelines remain in effect because authentication is required "The next time the prescribing practitioner provides care to the patient, assesses the patient, or documents information in the patient's medical record" and the burden of bringing these orders to the attention of the prescribing practitioner will undoubtedly fall to the nurses.

Nurses rarely complain about tasks which benefit patients. However, many healthcare professionals see the short time frame for the authentication of verbal orders as an unnecessary regulatory requirement that provides little, if any, patient benefit. While no study has identified telephone/verbal orders as a significant cause of medication errors, studies have found that distraction and workload are significant contributing factors to such errors.

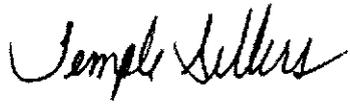
The change in Georgia's rules went into effect in December of 2002, and since that time, there have been no problems identified as a result of the extended time frame for authentication. To the contrary, the rules have been a resounding success, freeing nurses to provide patient care services, reducing tensions between nursing staff and physicians and improving awareness of patient safety as providers implement the "repeat and verify" process.

GHA strongly urges CMS to cease implementation of the new interpretive guidelines related to the authentication of verbal orders. To do otherwise will result in the untenable situation in which Georgia hospitals will be required to create and implement a new authentication policy this year to comply with the new interpretive guidelines and then will have to change their policies back once CMS adopts its proposed rule. This type of inconsistency, especially as it relates to the relationship between the hospital's nursing staff and its physicians, is not in anyone's best interest, including patients.

GHA also requests clarification that Georgia's regulation as described herein is sufficient to comply with the proposed language requiring state law to designate a "specific time frame for the authentication of verbal orders." Georgia's licensure rules provide hospitals with a choice. If a hospital chooses not to implement the repeat and verify process, verbal orders must be authenticated within 48 hours. If a hospital implements a repeat and verify process it must obtain authentication within 30 days after discharge but may require authentication within a shorter time frame if it so desires. GHA is concerned that this flexibility may be interpreted to fall short of the "specific time frame" required by the proposed rule.

Thank you again for the opportunity to comment on these proposed hospital CoPs.

Sincerely,

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

Temple Sellers
Vice President of Legal Services

Submitter :

Date: 05/24/2005

Organization :

Category : Hospital

Issue Areas/Comments

Issue

Timeframe for authentication of verbal orders

Members of our medical staff stated the requirement to have verbal orders authenticated within 48 hours would cause significant "bottle-necking" at time of discharge and would increase the patient's length of stay. They felt this requirement would place significant undue burden on both the hospital and the physician. There was concern that if this rule was implemented any order that was not signed within 48 hours might become invalid and cause real problems with insurance fraud. They also pointed out this would eliminate their ability to electronically complete this portion of the medical record

Timeframe for completion of the medical history and physical examination

They agree with the no more than 30 days or 24 hours after admission

Medical staff (482.22)

Members of our medical staff said this would be a very difficult requirement for them to enforce. They see no reason to require documentation if there has been no change in the patient's condition. They agree if a change has occurred a note should be made

Nursing services (482.23)

There is already a more rigorous process for verbal orders with the required "Read back verification" process

Submitter : Dr. Larry Laurich
Organization : Dr. Larry Laurich
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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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,

Larry Laurich D.P.M.

Submitter : Dr. Jerome Schoffler
Organization : American Podiatric Medical Association
Category : Physician

Date: 05/24/2005

Issue Areas/Comments

GENERAL

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See Attachment

CMS-3122-P-376-Attach-1.DOC

RE: CMS-3122-P

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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. Kris Bjornson
Organization : Anesthesia Service Medical Group, Inc.
Category : Physician

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-3122-P-377-Attach-1.DOC

Anesthesia Service Medical Group, Inc.
3626 Ruffin Road
San Diego, CA 92123
(858) 565-9666

May 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3122-P
Via Electronic Mail

Re: Proposed Rule Concerning Hospital Conditions of Participation
CMS-3122-P

To Whom It May Concern:

I am writing on behalf of Anesthesia Service Medical Group, Inc. ("ASMG"), a medical group in San Diego, California that is comprised of 183 physicians who specialize in the provision of anesthesia and pain management services. The physicians of ASMG believe it is important to express our support for several modifications the Centers for Medicare and Medicaid Services ("CMS") is proposing to its Hospital Conditions of Participation.

Specifically, ASMG would like to express its support for the sections of the proposed rule relating to 1) completion of the medical history and physical examination, 2) securing medications, and 3) completion of the postanesthesia evaluation.

Completion of the Medical History and Physical Examination

Although the section of the proposed rule concerning histories and physicals ("H&P") does not directly relate to anesthesiologists, ASMG physicians are often indirectly impacted by current regulations that require all patients to have an H&P completed by either a Doctor of Medicine ("M.D.") or a Doctor of Osteopathy ("D.O."). Because the current regulation does not allow a podiatrist to conduct an H&P on their own patients, members of ASMG are often asked to perform H&Ps that are beyond the scope of the preoperative examination normally conducted by an anesthesiologist. In addition, we are asked to perform H&Ps for patients with which we may not otherwise have any involvement. This places ASMG physicians in the difficult position of either refusing to perform an H&P – which could result in a procedure being cancelled, a significant cause of inconvenience and stress for a patient – or agreeing to conduct the H&P and accept the additional malpractice risk. As you can imagine, neither option is very appealing.

In light of our concerns, ASMG strongly supports CMS' proposed rule change that would allow H&Ps to be completed by a non-physician, as long as they are permitted to do so under State law and they have been granted the appropriate privileges by a hospital to perform these procedures. Since California has already approved allowing podiatrists to

Centers for Medicare and Medicaid Services
May 24, 2005
Page Two

conduct H&Ps on their patients, we believe this rule modification will help remove ASMG physicians from this difficult position.

Securing Medications

ASMG also supports CMS' proposed modifications to the regulations governing the security of anesthesia carts. As CMS indicates in its overview of the proposed rule, anesthesiologists typically open their anesthesia carts prior to a procedure and need to continually access them throughout the day's procedures. The current requirement that the carts be locked, unless in immediate use, is cumbersome and can impair our access to the many non-controlled medications that are necessary for the safe management of patients. In other words, we believe the current regulations represent a direct threat to patient care. Furthermore, a locked cart only minimally increases the security of the medications it contains because an unlocked cart remains under the careful watch of the anesthesiologist and other operating room personnel.

We fully support keeping controlled medications locked when not in use, and believe that the proposed requirement that non-controlled medications remain secure, but not necessarily locked, at all times, is an appropriate balance between patient safety and the security of medications. We appreciate CMS working with the American Society of Anesthesiologists ("ASA") to draft this modification.

Completion of the Postanesthesia Evaluation

The final item in the proposed rule that ASMG would like to comment on concerns the completion of the postanesthesia evaluation. As you know, the current rule requires the person who administers anesthesia to document a follow-up note in the patient's chart within 48 hours of surgery. This rule places a burden on physicians because the physician who provided anesthesia may be off the schedule for the subsequent 48 hours and is often unable to make a notation in the chart immediately following the procedure due to the pressures to keep operating rooms running at full efficiency. The proposed change, however, alleviates these concerns by allowing a different physician to follow up with the previous day's patients. As proposed, the rule would more accurately reflect the realities we face in anesthesia practice, without compromising the quality of care we deliver to our patients.

On behalf of ASMG, I appreciate the opportunity to comment on CMS' proposed changes to its Hospital Conditions of Participation.

Sincerely,

[Submitted Electronically]

Kris M. Bjornson, M.D.
President, ASMG Board of Directors

Submitter : Dr. joseph doctora
Organization : oms specialists, pllc
Category : Other Health Care Professional

Date: 05/24/2005

Issue Areas/Comments

GENERAL

GENERAL

I am an oral & maxillofacial surgeon and have reviewed the proposed change to the CMS Conditions of Participation (CoP) related to H&P's that would allow this service to be performed by a physician as defined by the social security act. the social security act defines physicians as doctors of medicine or osteopathy, doctors of dental surgery or dental medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors. although i support the use of this definition in most contexts, i am concerned that applying this definition to the H&P will cause hospital medical staffs to limit this privilege exclusively to MD/DO's and as a result, negatively impact patient care. some medical staffs are already attempting to change their bylaws to limit this privilege to MD/DO's, often because of their unfamiliarity with the education and training standards of non MD practitioners. limitations or withdrawal of oral surgeons H&P privileges would limit access for my patients, as well as maxillofacial trauma patients who would require my services, and would threaten the accreditation of the 100 accredited oral surgery residency training programs.

i understand the motivation for using the social security acts definition in the CoP is a result of concerns brought to your attention by podiatrists. podiatrists with advanced training may be qualified to perform an H&P. i oppose this change and suggest that the CoP should be revised to include MD/DO Oral & maxillofacial surgeons for oms patients and if they are trained to perform and complete an H&P, a doctor of podiatry who has completed a residency. thank you for consideration of these comments.

Joe Doctora, DDS, MD
Board certified Oral & maxillofacial surgeon

Submitter : Dr. Paul Lieberman

Date: 05/25/2005

Organization : Dr. Paul Lieberman

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

DR. PAUL S. LIEBERMAN
YOUR PERSONAL PROFESSIONAL FOOT CARE SPECIALIST
6779 MEMPHIS SUITE 4
BROOKLYN, Ohio 44144

TELEPHONE 216-351-3668
e-mail idpm@aol.com

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,

Paul S. Lieberman D.P.M.

Submitter : Ms. Regina Hardy

Date: 05/25/2005

Organization : Novant Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

These changes would help to ease the regulatory burden on hospitals. Please also consider the thirty-minute medication rule and the applicability to all medications.