



December 14, 2007

Dayle D. Stepp, Director  
Certificate of Need Program  
West Virginia Health Care Authority  
100 Dee Drive  
Charleston, West Virginia 25311

Re: Comments to Proposed Cardiac Catheterization Standards

Dear Mr. Stepp:

On behalf of Camden-Clark Memorial Hospital ("CCMH"), we respectfully submit this letter in response to the West Virginia Health Care Authority's ("Authority") proposed Certificate of Need Standards for Cardiac Catheterization released for public comment on November 14, 2007. As the largest provider of acute care hospital services in the Mid-Ohio Valley region, CCMH remains vitally interested in the availability and accessibility of needed cardiac services. CCMH also operates the busiest single site emergency room in the Mid-Ohio Valley. During its most recently completed fiscal year, CCMH experienced approximately 47,000 visits to its emergency room, resulting in almost 8,400 admissions therefrom.

As a general comment, CCMH is pleased that the Authority has proposed CON Standards which allow the development of Therapeutic Cardiac Catheterization services on a permanent basis at hospitals without on-site cardiac surgery. We believe that the experience gained by the Authority from its recent Demonstration Pilot Project overwhelmingly supports this decision from a patient safety standpoint. CCMH also shares the view of the Authority that it is important to make the life-saving procedure of Primary Percutaneous Coronary Intervention ("Primary PCI") available on a more widespread basis to hospitals throughout the state. This is especially appropriate given West Virginia's high incidence of cardiovascular disease and mortality compared to the rest of the nation. Although CCMH shares many of the same views of the Authority on this topic, the comments which it provides below are believed to be necessary in order to make Therapeutic Cardiac Catheterization more readily available to patients without compromising either quality or cost.

1. Article IV, Paragraph B(1). The proposed Standards require an applicant for Primary PCI to have performed an average of 300 Diagnostic Cardiac Catheterization procedures annually during the most three-year period preceding the date that the application is submitted. CCMH's primary comment here is that the performance of a specified number of Diagnostic Cardiac Catheterization procedures is not generally associated with the competency and quality of Primary PCI services. Three different publications, namely (a) "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards," (b) "ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention," and (c) "ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac Interventional Procedures," all recommend a volume threshold of 75 interventional procedures

per year for physicians performing PCI. None of these scholarly reports discuss or even mention the performance of a specified number of Diagnostic Cardiac Catheterization procedures as being a relevant consideration to the quality of either a Primary or Elective PCI service. Although the 75 threshold number is for interventional procedures, given the fact that interventional procedures are more complex than Diagnostic Cardiac Catheterization procedures, CCMH recommends that the 300 procedure threshold in Article IV, Paragraph B(1) be reduced to no more than 150 Diagnostic Cardiac Catheterization procedures annually during the most recent three-year period preceding the date that the application is submitted.

2. Article IV, Paragraph B(6). CCMH is in general agreement that a written transfer agreement should be in place between any hospital wishing to perform Therapeutic Cardiac Catheterization procedures, and a cardiac surgery hospital. CCMH contends that a standard transfer agreement between hospitals should suffice to meet this requirement. Such agreements are currently in place, and have been successfully relied upon for years to govern the transfer of emergency/trauma/high risk patients on an ongoing, daily basis. The rights and responsibilities of transferring and receiving hospitals in these circumstances are also specifically governed by federal law under the Emergency Medical Treatment and Active Labor Act (“EMTALA”) as codified at 42 U.S.C. § 1395dd, and in regulations at 42 C.F.R. § 489.24. Copies of the statute and regulation are attached in Exhibits A and B. They contain a host of specific requirements, and place hospitals at risk of severe civil penalties and/or loss of Medicare participation rights for failure to properly handle patient transfers. Accordingly, the Authority’s recommended development of a technically-detailed agreement between a hospital wishing to provide Therapeutic Cardiac Catheterization services and a cardiac surgery hospital is unnecessary. Moreover, these detailed requirements will inevitably lead to contentious, time-consuming, and deadlocked negotiations over the agreement itself. CCMH recommends that the requirements for this written agreement be substantially amended and simplified. CCMH has suggested alternative language to address the transfer agreement requirement in attached Exhibit C.

3. Article IV, Paragraph B(6)(a). This provision of the proposed Standards requires the written agreement to address involvement in credentialing criteria and recommendations for physicians approved to perform Primary PCI. The apparent meaning of this provision is to allow the cardiac surgery hospital to have involvement in credentialing criteria and recommendations for physicians at the non-cardiac surgery hospital. This language is inconsistent with the legislative rules entitled “Hospital Licensure,” 64 C.S.R.12, § 11.1, *et seq.*, as well as the confidentiality requirements applicable to peer review organizations codified at W. Va. Code §30-3C-3. This provision is also inconsistent with the requirements of the Joint Commission on the Accreditation of Health Care Organizations (“JCAHO”), which mandates that the granting of medical staff privileges be based upon criteria specified in a hospital’s medical staff bylaws. Credentialing is an institution-specific endeavor, subject to the final approval of the relevant hospital’s governing board. CCMH objects to any requirement that it delegate its authority over credentialing, either in whole or in part, to another institution. Accordingly, CCMH recommends deletion of this provision in its entirety.

4. Article IV, Paragraph B(6)(b). The requirement for the cross-training of staff to ensure familiarity with interventional equipment is not necessarily a useful requirement for any written agreement if the two hospitals do not have similar equipment. This provision should be deleted as a requirement of any written agreement.

5. Article IV, Paragraph B(6)(d). The requirement for regularly-held joint cardiology/cardiac surgery conferences, including review of all Primary PCI cases, again presents a legal problem involving institutional autonomy, and a hospital's ability to maintain the confidentiality of its peer review processes under W. Va. Code §30-3C-3. CCMH believes that the Authority must recognize that the hospitals have independent governing bodies, medical staffs, and bylaws. CCMH further believes that there will be a real reluctance for one hospital to become involved in the peer review activities of another, and that the statutory privilege granted to peer review proceedings will be compromised. Accordingly, CCMH recommends that this provision be deleted in its entirety.

6. Article IV, Paragraph B(6)(e)-(j). Each of the items discussed in these subparagraphs may be appropriate criteria to be considered by a hospital wishing to provide Therapeutic Cardiac Catheterization services, but none of them need to be included within the written agreement between that hospital and the cardiac surgery hospital. These subparagraphs must be removed from Paragraph B(6).

7. CCMH believes that the proposed Standards should include an appropriate incentive for a cardiac surgery hospital to enter into a written agreement with a hospital in the same community wishing to provide Primary PCI. It is important for hospitals in close proximity to work cooperatively to ensure that Primary PCI is provided to area residents effectively and safely. CCMH believes that if a local cardiac surgery hospital refuses to enter into a written transfer agreement with an applicant for Primary PCI within the same community, then the three-year waiting period for elective Therapeutic Cardiac Catheterization services should be waived. This can be justified because the non-cardiac surgery hospital without a local transfer agreement has a greater need to develop a full-fledged Therapeutic Cardiac Catheterization program of its own. Specifically, the non-cardiac surgery hospital will have more trouble attracting cardiologists, maintaining trained staff, and ensuring full-time 24/7/365 responsiveness without local support and backup. CCMH therefore recommends that the Authority consider incorporating such a waiver, and suggests the language set forth in attached Exhibit C.

Thank you for the opportunity of providing these comments to the Authority on this most important question. Please feel free to contact us should you require clarification of our comments, or if we may be of any other assistance to you in this matter.

Sincerely,



Michael A. King  
President and CEO

**EXHIBIT A**

(Insert 42 U.S.C. §1395dd)

health care delivery and changing the allocation of resources; and

(3) meet such other requirements as the Secretary may establish.

**(e) Waiver authority**

The Secretary may waive such requirements of subchapters XI and XVIII of this chapter as may be necessary to carry out the purposes of the demonstration program established under this section.

**(f) Budget neutrality**

With respect to the 5-year period of the demonstration program under subsection (b) of this section, the aggregate expenditures under this subchapter for such period shall not exceed the aggregate expenditures that would have been expended under this subchapter if the program established under this section had not been implemented.

**(g) Notice requirements**

In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this subchapter as a result of the participation of the individual in such program.

**(h) Participation and support by Federal agencies**

In carrying out the demonstration program under this section, the Secretary may direct—

(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;

(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and

(3) the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant medicare data to registry information from participating health care groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstration program, consistent with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996.

(Aug. 14, 1935, c. 531, Title XVIII, § 1866C, as added Dec. 8, 2003, Pub.L. 108-173, Title VI, § 646, 117 Stat. 2324.)

**§ 1395dd. Examination and treatment for emergency medical conditions and women in labor**

[SSA § 1867]

**(a) Medical screening requirement**

In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the meaning of subsection (c)(1) of this section) exists.

**(b) Necessary stabilizing treatment for emergency medical conditions and labor**

**(1) In general**

If any individual (whether or not eligible for benefits under this subchapter) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or

(B) for transfer of the individual to another medical facility in accordance with subsection (c) of this section.

**(2) Refusal to consent to treatment**

A hospital is deemed to meet the requirement of paragraph (1)(A) with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of such examination and treatment, but the individual (or a person acting on the individual's behalf) refuses to consent to the examination and treatment. The hospital shall take all reasonable steps to secure the individual's (or person's) written informed consent to refuse such examination and treatment.

**(3) Refusal to consent to transfer**

A hospital is deemed to meet the requirement of paragraph (1) with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with subsection (c) of this section and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of such transfer, but the individual (or a person acting on the individual's behalf) refuses to consent to the transfer. The hospital shall take all reasonable steps to secure the

individual's (or person's) written informed consent to refuse such transfer.

**(c) Restricting transfers until individual stabilized**  
**(1) Rule**

If an individual at a hospital has an emergency medical condition which has not been stabilized (within the meaning of subsection (e)(3)(B) of this section), the hospital may not transfer the individual unless—

(A)(i) the individual (or a legally responsible person acting on the individual's behalf) after being informed of the hospital's obligations under this section and of the risk of transfer, in writing requests transfer to another medical facility.

(ii) a physician (within the meaning of section 1395x(r)(1) of this title) has signed a certification that<sup>1</sup> based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child from effecting the transfer, or

(iii) if a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as defined by the Secretary in regulations) has signed a certification described in clause (ii) after a physician (as defined in section 1395x(r)(1) of this title), in consultation with the person, has made the determination described in such clause, and subsequently countersigns the certification; and

(B) the transfer is an appropriate transfer (within the meaning of paragraph (2)) to that facility.

A certification described in clause (ii) or (iii) of subparagraph (A) shall include a summary of the risks and benefits upon which the certification is based.

**(2) Appropriate transfer**

An appropriate transfer to a medical facility is a transfer—

(A) in which the transferring hospital provides the medical treatment within its capacity which minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(B) in which the receiving facility—

(i) has available space and qualified personnel for the treatment of the individual, and

(ii) has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(C) in which the transferring hospital sends to the receiving facility all medical records (or copies thereof), related to the emergency condition for which the individual has presented, available at

the time of the transfer, including records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) provided under paragraph (1)(A), and the name and address of any on-call physician (described in subsection (d)(1)(C) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment;

(D) in which the transfer is effected through qualified personnel and transportation equipment, as required including the use of necessary and medically appropriate life support measures during the transfer; and

(E) which meets such other requirements as the Secretary may find necessary in the interest of the health and safety of individuals transferred.

**(d) Enforcement**

**(1) Civil money penalties**

(A) A participating hospital that negligently violates a requirement of this section is subject to a civil money penalty of not more than \$50,000 (or not more than \$25,000 in the case of a hospital with less than 100 beds) for each such violation. The provisions of section 1320a-7a of this title (other than subsections (a) and (h)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply with respect to a penalty or proceeding under section 1320a-7a(a) of this title.

(B) Subject to subparagraph (C), any physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on-call for the care of such an individual, and who negligently violates a requirement of this section, including a physician who—

(i) signs a certification under subsection (c)(1)(A) of this section that the medical benefits reasonably to be expected from a transfer to another facility outweigh the risks associated with the transfer, if the physician knew or should have known that the benefits did not outweigh the risks, or

(ii) misrepresents an individual's condition or other information, including a hospital's obligations under this section,

is subject to a civil money penalty of not more than \$50,000 for each such violation and, if the violation is gross and flagrant or is repeated, to exclusion from participation in this subchapter and State health care programs. The provisions of section 1320a-7a of this title (other than the first and second sentences of subsection (a) and subsection (b)) shall apply to a civil money penalty and exclusion under

this subparagraph in the same manner as such provisions apply with respect to a penalty, exclusion, or proceeding under section 1320a-7a(a) of this title.

(C) If, after an initial examination, a physician determines that the individual requires the services of a physician listed by the hospital on its list of on-call physicians (required to be maintained under section 1395cc(a)(1)(1) of this title) and notifies the on-call physician and the on-call physician fails or refuses to appear within a reasonable period of time, and the physician orders the transfer of the individual because the physician determines that without the services of the on-call physician the benefits of transfer outweigh the risks of transfer, the physician authorizing the transfer shall not be subject to a penalty under subparagraph (B). However, the previous sentence shall not apply to the hospital or to the on-call physician who failed or refused to appear.

**(2) Civil enforcement**

**(A) Personal harm**

Any individual who suffers personal harm as a direct result of a participating hospital's violation of a requirement of this section may, in a civil action against the participating hospital, obtain those damages available for personal injury under the law of the State in which the hospital is located, and such equitable relief as is appropriate.

**(B) Financial loss to other medical facility**

Any medical facility that suffers a financial loss as a direct result of a participating hospital's violation of a requirement of this section may, in a civil action against the participating hospital, obtain those damages available for financial loss, under the law of the State in which the hospital is located, and such equitable relief as is appropriate.

**(C) Limitations on actions**

No action may be brought under this paragraph more than two years after the date of the violation with respect to which the action is brought.

**(3) Consultation with peer review organizations**

In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) or in terminating a hospital's participation under this subchapter, the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of subchapter XI of this chapter) to assess whether the individual involved had an emergency medical condition which had not been stabi-

lized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this subchapter for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B of subchapter XI of this chapter.

**(4) Notice upon closing an investigation**

The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.

**(e) Definitions**

In this section:

(1) The term "emergency medical condition" means—

(A) a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

(ii) serious impairment to bodily functions,

or

(iii) serious dysfunction of any bodily organ or part; or

(B) with respect to a pregnant woman who is having contractions—

(i) that there is inadequate time to effect a safe transfer to another hospital before delivery, or

(ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

(2) The term "participating hospital" means a hospital that has entered into a provider agreement under section 1395cc of this title.

(3)(A) The term "to stabilize" means, with respect to an emergency medical condition described in paragraph (1)(A), to provide such medical treatment of the condition as may be necessary to as-

sure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition described in paragraph (1)(B), to deliver (including the placenta).

(B) The term "stabilized" means, with respect to an emergency medical condition described in paragraph (1)(A), that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition described in paragraph (1)(B), that the woman has delivered (including the placenta).

(4) The term "transfer" means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (A) has been declared dead, or (B) leaves the facility without the permission of any such person.

(5) The term "hospital" includes a critical access hospital (as defined in section 1395x(mm)(1) of this title).

#### (f) Preemption

The provisions of this section do not preempt any State or local law requirement, except to the extent that the requirement directly conflicts with a requirement of this section.

#### (g) Nondiscrimination

A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

#### (h) No delay in examination or treatment

A participating hospital may not delay provision of an appropriate medical screening examination required under subsection (a) of this section or further medical examination and treatment required under subsection (b) of this section in order to inquire about the individual's method of payment or insurance status.

#### (i) Whistleblower protections

A participating hospital may not penalize or take adverse action against a qualified medical person described in subsection (c)(1)(A)(iii) or a physician because the person or physician refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized or against any

hospital employee because the employee reports a violation of a requirement of this section.

(Aug. 14, 1935, c. 531, Title XVIII, § 1867, as added Apr. 7, 1986, Pub.L. 99-272, Title IX, § 9121(b), 100 Stat. 164, and amended Oct. 21, 1986, Pub.L. 99-509, Title IX, § 9307(c)(4), 100 Stat. 1996; Oct. 22, 1986, Pub.L. 99-514, Title XVIII, § 1895(b)(4), 100 Stat. 2933; Dec. 22, 1987, Pub.L. 100-203, Title IV, § 4009(a), 101 Stat. 1330-56, 1330-57; Dec. 22, 1987, Pub.L. 100-203, Title IV, § 4009(a)(1), formerly § 4009(a)(1), (2), 101 Stat. 1330-56, 1330-57; renumbered and amended July 1, 1988, Pub.L. 100-360, Title IV, § 411(b)(8)(A)(i), 102 Stat. 771; Oct. 13, 1988, Pub.L. 100-485, Title VI, § 609(d)(18)(E), 102 Stat. 2419; Dec. 19, 1989, Pub.L. 101-239, Title VI, §§ 6003(g)(3)(D)(xiv), 6211(a) to (h), 103 Stat. 2154, 2245; Nov. 5, 1990, Pub.L. 101-508, Title IV, §§ 4068(b)(1) to (3)(A), 4207(a)(1)(A), (2), (3), (k)(3), 104 Stat. 1388-44, 1388-117, 1388-124; renumbered and amended Oct. 31, 1994, Pub.L. 103-432, Title I, § 160(d)(4), (5)(A), 108 Stat. 4444; Aug. 5, 1997, Pub.L. 105-33, Title IV, § 4201(c)(1), 111 Stat. 373; Dec. 8, 2003, Pub.L. 108-173, Title VII, § 736(a)(14), Title IX, § 944(b), (c)(1), 117 Stat. 2355, 2423.)

1 So in original. Probably should be followed by a comma.

### § 1395ee. Practicing Physicians Advisory Council; Council for Technology and Innovation

[SSA § 1868]

#### (a) Practicing Physicians Advisory Council

##### (1) Appointment

The Secretary shall appoint, based upon nominations submitted by medical organizations representing physicians, a Practicing Physicians Advisory Council (in this subsection referred to as the "Council") to be composed of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under this subchapter in the previous year. At least 11 of the members of the Council shall be physicians described in section 1395x(r)(1) of this title and the members of the Council shall include both participating and nonparticipating physicians and physicians practicing in rural areas and underserved urban areas.

##### (2) Meetings

The Council shall meet once during each calendar quarter to discuss certain proposed changes in regulations and carrier manual instructions related to physician services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, such consultation shall occur before the publication of such proposed changes.

##### (3) Reimbursement of expenses

Members of the Council shall be entitled to receive reimbursement of expenses and per diem in lieu of subsistence in the same manner as other members of advisory councils appointed by the Secretary are provided such reimbursement and per diem under this subchapter.

**EXHIBIT B**

(Insert 42 C.F.R. §489.24)

chapter) for which Medicare payment would be made if furnished by the hospital or by other providers or suppliers under arrangements made with them by the hospital. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the hospital for the item or service, and is also prohibited.

(g) [Reserved]

(h) Items and services (other than those described in §§ 489.20(s)(1) through (15)) required to be furnished under § 489.20(s) to a resident of a SNF (defined in § 411.15(p) of this chapter), for which Medicare payment would be made if furnished by the SNF or by other providers or suppliers under arrangements made with them by the SNF. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the SNF for the item or service, and is also prohibited. [45 FR 22937, April 4, 1980; 48 FR 39833, Sept. 1, 1983; 49 FR 324, Jan. 3, 1984; 51 FR 22052, June 17, 1986; 52 FR 27765, July 23, 1987; 60 FR 63189, Dec. 8, 1995; 64 FR 41683, July 30, 1999; 65 FR 46796, July 31, 2000; 65 FR 62646, Oct. 19, 2000; 66 FR 39601, July 31, 2001]

#### § 489.22 Special provisions applicable to prepayment requirements.

(a) A provider may not require an individual entitled to hospital insurance benefits to prepay in part or in whole for inpatient services as a condition of admission as an inpatient, except where it is clear upon admission that payment under Medicare, Part A cannot be made.

(b) A provider may not deny covered inpatient services to an individual entitled to have payment made for those services on the ground of inability or failure to pay a requested amount at or before admission.

(c) A provider may not evict, or threaten to evict, an individual for inability to pay a deductible or a coinsurance amount required under Medicare.

(d) A provider may not charge an individual for (1) its agreement to admit or readmit the individual on some specified future date for covered inpatient services; or (2) for failure to remain an inpatient for any agreed-upon length of time or for failure to give advance notice of departure from the provider's facilities.

[68 FR 46072, Aug. 4, 2003]

#### § 489.23 Specific limitation on charges for services provided to certain enrollees of fee-for-service FEHB plans.

A provider that furnishes inpatient hospital services to a retired Federal worker age 65 or older who is enrolled in a fee-for-service FEHB plan and who is not covered under Medicare Part A, must accept, as payment in full, an amount that approximates as closely as possible the Medicare inpatient hospital prospective payment system (PPS) rate established

under part 412. The payment to the provider is composed of a payment from the FEHB plan and a payment from the enrollee. This combined payment approximates the Medicare PPS rate. The payment from the FEHB plan approximates, as closely as possible, the Medicare PPS rate minus any applicable enrollee deductible, coinsurance, or copayment amount. The payment from the enrollee is equal to the applicable deductible, coinsurance, or copayment amount.

[62 FR 56110, Oct. 29, 1997]

#### § 489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) Applicability of provisions of this section.

(1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must—

(i) Provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of § 482.55 of this chapter concerning emergency services personnel and direction; and

(ii) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2) Nonapplicability of provisions of this section. Sanctions under this section for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act.

(b) Definitions. As used in this subpart—

Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

Comes to the emergency department means, with respect to an individual who is not a patient (as defined in this section), the individual—

(1) Has presented at a hospital's dedicated emergency department, as defined in this section, and requests examination or treatment for a medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs examination or treatment for a medical condition;

(2) Has presented on hospital property, as defined in this section, other than the dedicated emergency department, and requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs emergency examination or treatment;

(3) Is in a ground or air ambulance owned and operated by the hospital for purposes of examination and treatment for a medical condition at a hospital's dedicated emergency department, even if the ambulance is not on hospital grounds. However, an individual in an ambulance owned and operated by the hospital is not considered to have "come to the hospital's emergency department" if—

(i) The ambulance is operated under community-wide emergency medical service (EMS) protocols that direct it to transport the individual to a hospital other than the hospital that owns the ambulance; for example, to the closest appropriate facility. In this case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property;

(ii) The ambulance is operated at the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance; or

(4) Is in a ground or air nonhospital-owned ambulance on hospital property for presentation for examination and treatment for a medical condition at a hospital's dedicated emergency department. However, an individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. The hospital may direct the ambulance to another facility if it is in "diversionary status," that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff

disregards the hospital's diversion instructions and transports the individual onto hospital property, the individual is considered to have come to the emergency department.

Dedicated emergency department means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

(1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

(2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

(3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

Emergency medical condition means—

(1) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part; or

(2) With respect to a pregnant woman who is having contractions—

(i) That there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) That transfer may pose a threat to the health or safety of the woman or the unborn child.

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act.

Hospital property means the entire main hospital campus as defined in § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures of the hospital's main building that are not part of the hospital, such as physician offices, rural health centers, skilled nursing facilities, or other entities that participate separately under Medicare, or restaurants, shops, or other non-medical facilities.

Hospital with an emergency department means a hospital with a dedicated emergency department as defined in this paragraph (b).

Inpatient means an individual who is admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services as described in § 409.10(a) of this chapter with the expectation that he or she will remain at least overnight and occupy a bed even though the situation later develops that the individual can be discharged or transferred to another hospital and does not actually use a hospital bed overnight.

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician certifies that, after a reasonable time of observation, the woman is in false labor.

Participating hospital means (1) a hospital or (2) a critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Patient means—

(1) An individual who has begun to receive outpatient services as part of an encounter, as defined in § 410.2 of this chapter, other than an encounter that the hospital is obligated by this section to provide;

(2) An individual who has been admitted as an inpatient, as defined in this section.

Stabilized means, with respect to an "emergency medical condition" as defined in this section under paragraph (1) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an "emergency medical condition" as defined in this section under paragraph (2) of that definition, that the woman has delivered the child and the placenta.

To stabilize means, with respect to an "emergency medical condition" as defined in this section under paragraph (1) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an "emergency medical condition" as defined in this section under paragraph (2) of that definition, the woman has delivered the child and the placenta.

Transfer means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual

who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person.

(c) Use of dedicated emergency department for nonemergency services. If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

(d) Necessary stabilizing treatment for emergency medical conditions.—

(1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.

(ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) Exception: Application to inpatients.

(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual.

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment. A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take

all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

(4) Delay in examination or treatment.

(i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status.

(ii) A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

(iv) Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

(5) Refusal to consent to transfer. A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a descrip-

tion of the proposed transfer that was refused by or on behalf of the individual.

(e) Restricting transfer until the individual is stabilized—

(1) General. If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (c)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which—

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility—

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the

individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

(f) Recipient hospital responsibilities. A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.

(g) Termination of provider agreement. If a hospital fails to meet the requirements of paragraph (a) through (f) of this section, CMS may terminate the provider agreement in accordance with § 489.53.

(h) Consultation with Quality Improvement Organizations (QIOs)—

(1) General. Except as provided in paragraph (h)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under section 1867(d)(1) of this Act, CMS requests the appropriate QIO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (h)(2)(iv) and (v) of this section. CMS provides to the QIO all information relevant to the case and within its possession or control. CMS, in consultation with the OIG, also provides to the QIO a list of relevant questions to which the QIO must respond in its report.

(2) Notice of review and opportunity for discussion and additional information. The QIO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a QIO receives a request for consultation under paragraph (h)(1) of this section, the following provisions apply—

(i) The QIO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the QIO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii)(A) The written notice must contain the following information:

(1) The name of each individual who may have been the subject of the alleged violation.

(2) The date on which each alleged violation occurred.

(3) An invitation to meet, either by telephone or in person, to discuss the case with the QIO, and to submit additional information to the QIO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not accepted. The QIO must receive the information and hold the meeting within the 30-day period.

(4) A copy of the regulations at 42 CFR 489.24.

(B) For purposes of paragraph (h)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the QIO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the QIO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The QIO may also have legal counsel present.

(B) The QIO makes arrangements so that, if requested by CMS or the OIG, a verbatim transcript of the meeting may be generated. If CMS or OIG requests a transcript, the affected physician and/or the affected hospital may request that CMS provide a copy of the transcript.

(C) The QIO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the QIO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The QIO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the QIO requests that the physician and/or hospital submit additional information to support the claims. The QIO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the QIO.

(v) Within 60 calendar days of receiving the case, the QIO must submit to CMS a report on the QIO's findings. CMS provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case.

(vi) The report required under paragraph (h)(2)(v) of this section should not state an opinion or conclusion as to whether section 1867 of the Act or § 489.24 has been violated.

(3) If a delay would jeopardize the health or safety of individuals or when there was no screening examination, the QIO review described in this section is not required before the OIG may impose civil monetary penalties or an exclusion in accordance with section 1867(d)(1) of the Act and 42 CFR part 1003 of this title.

(4) If the QIO determines after a preliminary review that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, as defined by paragraph (b) of this section, then the QIO may, at its discretion, return the case to CMS and not meet the requirements of paragraph (h) except for those in paragraph (h)(2)(v).

(i) Release of QIO assessments. Upon request, CMS may release a QIO assessment to the physician and/or hospital, or the affected individual, or his or

her representative. The QIO physician's identity is confidential unless he or she consents to its release. (See §§ 476.132 and 476.133 of this chapter.)

(j) Availability of on-call physicians.

(1) Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

(2) The hospital must have written policies and procedures in place—

(i) To respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control; and

(ii) To provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

[62 FR 46037, Aug. 29, 1997; 65 FR 18548, April 7, 2000; 65 FR 40535, June 30, 2000; 65 FR 58919, Oct. 3, 2000; 65 FR 59748, Oct. 6, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59923, Nov. 30, 2001; 68 FR 53262, Sept. 9, 2003]

**§ 489.25 Special requirements concerning CHAMPUS and CHAMPVA programs.**

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted under 10 U.S.C. 1079 or 1086 (Civilian Health and Medical Program of the Uniformed Services) and under 38 U.S.C. 613 (Civilian Health and Medical Program of the Veterans Administration) and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items. Hospitals must meet the requirements of 32 CFR part 199 concerning program benefits under the Department of Defense. This section applies to inpatient services furnished to beneficiaries admitted on or after January 1, 1987.

[59 FR 32123, June 22, 1994]

**§ 489.26 Special requirements concerning veterans.**

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs under 38 U.S.C. 603 and must meet the requirements of 38 CFR part 17 concerning admissions practices and payment methodology and amounts. This section applies to services furnished to veterans admitted on and after July 1, 1987.

[59 FR 32123, June 22, 1994]

**EXHIBIT C**

6. A written agreement with a Cardiac Surgery facility shall be submitted to the HCA which addresses the appropriate transfer of patients to the Cardiac Surgery facility in a manner that is consistent with the requirements of the Emergency Medical Treatment and Active Labor Act (42 U.S.C. §1395dd), and which addresses the minimization of duplicative procedures and the advancement of performance improvement through joint training and education efforts. The Authority encourages the West Virginia Cardiac Surgery facility in closest proximity to the applicant to develop and execute such a written agreement. If the West Virginia Cardiac Surgery facility in closest proximity to the applicant is presented with a written request for such an agreement at least 30 days before the applicant files its application to provide Primary PCI, and the West Virginia Cardiac Surgery facility refuses or fails to execute such an agreement on or before the date that the applicant actually files its application, then the Authority shall waive the condition set forth in Article IV(C)(1) applicable to elective Therapeutic Cardiac Catheterization services, and permit the applicant at its discretion to amend its application to include the provision of elective Therapeutic Cardiac Catheterization services.