



**Centers for Medicare & Medicaid Services
FY 2005 Inpatient Prospective Payment System
Notice of Proposed Rulemaking
Critical Access Hospital Issues**

The Centers for Medicare & Medicaid Services (CMS) issued a notice of proposed rulemaking (NPRM) in the May 18 *Federal Register* proposing to revise the Medicare inpatient hospital prospective payment system (PPS). The rule also implements a number of provisions contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), including a number of regulatory changes affecting critical access hospitals (CAHs). The proposed rule can be accessed on the *Federal Register* website at http://www.access.gpo.gov/su_docs/fedreg/a040518c.html. A comment period is provided until 5 p.m. on July 12, 2004. When submitting comments, CMS requests that the specific “issue identifier” that precedes the section on which comments are being submitted is included. Written comments, one original and three copies, can be mailed to:

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1428-P
P.O. Box 8010
Baltimore, MD 21244-1850

Alternatively, comments (an original and three copies) may be hand-delivered to CMS at:

Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

OR

Room C5-14-03
Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Additionally electronic comments can be submitted to:

<http://www.accessdata.fda.gov/scripts/oc/dockets/commentdocket.cfm?AGENCY=CMS> or
www.regulations.gov.

Payment Amounts

Prior to the enactment of the MMA, Medicare provided payment to CAHs for inpatient, outpatient and skilled nursing facility services on the basis of costs. Section 405(a) of the MMA provides for payment at 101% of the reasonable cost of the CAH in providing these services, effective for services furnished during cost reporting periods beginning on or after January 1, 2004. The rule proposes to revise regulations to incorporate the change in the payment percentage made by the MMA.

Condition of Application for Special Professional Service Payment Adjustment

The Social Security Act provides for two methods of payment for outpatient CAH services. A CAH will be paid under a reasonable cost method unless it elects payment under an optional method, also known as method II. Under this option, the CAH submits bills for both facility and professional services to the

Building a healthier Iowa for 75 years!

fiscal intermediary and Medicare makes payment for the facility services at the same level that would apply under the reasonable cost method (increasing to 101% for cost reporting periods beginning on or after January 1, 2004), but services of professionals to outpatients are paid at 115% of the amount that would have otherwise been paid under the physician fee schedule. Section 405 of MMA amended the Social Security Act by specifying that CMS may not require, as a condition for a CAH to make an election of the optional method of payment, that each physician or other practioner providing professional services in the CAH must assign billing rights to the CAH with respect to the services. However, the optional payment method does not apply to those physicians and practioners who have not assigned such billing rights.

CMS proposes to revise regulations to implement the changes made by section 405(d)(1) of the MMA by specifying that a CAH may elect to be paid for outpatient services in any cost reporting period beginning on or after July 1, 2004 under the method II option. The agency also proposes to clarify that such an election must be made at least 30 days before the start of the cost reporting period for which the election is made. Further, the provision would apply to all services furnished to outpatients during that cost reporting period by a physician or other practioner who has reassigned his or her rights to bill for those services to the CAH in accordance with Medicare reassignment regulations.

Coverage of Costs for Certain Emergency Room On-Call Providers

Under existing regulations, Medicare payments to a CAH may include the costs of compensation and related costs of on-call emergency room physicians who are not present on the premises of a CAH, are not otherwise furnishing services, and are not on-call at any other provider or facility when determining the reasonable cost of outpatient CAH services. Section 405(b) of the MMA expands the reimbursement of on-call emergency room providers beyond physicians to include physician assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services furnished on or after January 1, 2005.

CMS is proposing to revise current regulations to include the expanded list of emergency room on-call providers for whom reimbursement for reasonable compensation and related costs in a CAH would be available. In addition, the agency is making a conforming change to regulations governing the standard for emergency room personnel who are on call under the CAH conditions of participation to include clinical nurse specialists.

Authorization of Periodic Interim Payments

Current Medicare law allows for payments to be made on a periodic interim payment (PIP) basis for specified covered Medicare services. Section 405(c)(1) of the MMA amends the statute by adding the ability for the program to provide for payments for inpatient services furnished by CAHs on a PIP basis, effective for payments made on or after July 1, 2004. The MMA also directs the Secretary to develop alternative methods for the timing of the payments under the PIP method. CMS states in the proposed rule that existing regulations already allow for payments under the PIP method to providers for certain Medicare covered services. Under the proposed rule, the agency is suggesting additions to these existing regulations to specify inpatient services furnished by CAHs as an additional type of covered service for which PIP is available, effective for payments made on or after July 1, 2004.

It has been a longstanding CMS policy that payment will be made biweekly under the PIP method, unless the provider requests a longer fixed interval (not to exceed 1 month) between payments. Further, the agency states that this provision grants adequate flexibility for the timing of payments under the PIP method to all qualifying providers, including CAHs. Under the proposed policy for CAHs, if a CAH chooses to receive its payments less frequently than biweekly, the CAH could inform its Medicare fiscal intermediary.

In summary, CMS is proposing to apply the same rules and procedures for payments under the PIP method that are applied to acute care hospitals and certain other Medicare providers. Therefore, CAHs, in applying for and receiving payments for inpatient services under the PIP provision, would be operating under the same rules as other providers for which PIP is available, including the flexibility in the timing of their payments.

Revision of Bed Limits

Prior to the enactment of the MMA, CAHs were restricted to 15 acute care beds and a total of 25 beds if the CAH had been granted swing-bed approval. The number of beds used at any time for acute care inpatient services could not exceed 15 beds. Section 405(e) of the Medicare prescription drug legislation amended the Social Security Act to allow CAHs a maximum of 25 acute care beds for inpatient services, regardless of the swing-bed approval. This amendment is effective on January 1, 2004 and applies to CAHs designated before, on, or after this date. However, section 405(e)(3) of the MMA also notes that any election made in accordance with the regulations promulgated to carry out the bed size amendments only applies prospectively. According to the CMS' interpretation provided in the proposed rule, the agency believes this to mean that the increased bed size limitation is to be applied prospectively after April 1, 2004, regardless of when the CAH was designated. Accordingly, CMS implemented this provision via a survey and certification letter on January 1, 2004. (See Survey and Certification Letter No. 0414, issued December 11, 2003.) Therefore, effective January 1, 2004, this provision allows any currently participating CAH, or applicant for CAH approval, to maintain up to 25 inpatient beds. If swing-bed approval has been granted, all 25 beds can be used interchangeably for acute care or swing-bed services. However, no CAH will be considered to have had 25 acute care beds prior to January 1, 2004.

NOTE: CMS issued revised regulations and interpretative guidelines for CAHs in late May 2004. Under the standard for the number of beds [4CFR 485.620(a)], the agency's interpretation indicates that the CAH may not have more than 25 beds that could be used for inpatient care. Further, any hospital-type bed located in area adjacent to any location where the bed could be used for inpatient care counts toward the 25 bed limit. The guidelines go on to list the types of beds that do not count toward the 25 bed limit, including examination or procedure tables; stretchers; operating room tables located in the operating room; beds in surgical recovery that are used exclusively for surgical patients during recovery from anesthesia; beds in an obstetric delivery room that are used exclusively for observation of OB patients in active labor and delivery of newborn infants; newborn bassinets and isolettes used for well baby boarders; stretchers in the emergency department; and beds in Medicare certified distinct part rehabilitation or psychiatric units. The guidance addresses observation patient services and states "beds, used by patients on observation status, that conform to the hospital-type beds previously discussed in this requirement, will be counted as part of the maximum bed count".

Authority to Establish Psychiatric and Rehabilitation Distinct Part Units

Section 405(g)(1) of the MMA modified the statutory requirements to allow CAHs to establish distinct part rehabilitation and psychiatric units of up to 10 beds each, which will not be included in the revised total 25 CAH bed count, effective for the cost reporting periods beginning on or after October 1, 2004. In addition, the average 96-hour stay does not apply to the 10 beds in the distinct part units and inpatient admissions; days of inpatient care in these distinct part units are not taken into account in determining the facility's compliance with the requirement for a facility-wide average length of stay that does not exceed 96 hours.

The law also requires that a distinct part rehabilitation or psychiatric unit of a CAH must meet the conditions of participation that would otherwise apply to the distinct part unit of a hospital if the distinct part unit were established by a non-CAH facility. Due to the MMA provision CAHs will now be permitted to operate distinct-part psychiatric and rehabilitation units, and CMS points out its interpretation of the law, consistent with this change, requires the same level of health and safety

protection for patients in distinct part units of a CAH that is currently required for patients in distinct part units operated by non-CAH hospital.

As CAHs were excluded from operating distinct part units prior to the enactment of the MMA, the CAH conditions of participation did not address the necessary requirements and standards for operating such units. Therefore, CMS is proposing that, in accordance with the requirements of section 405(g), a rehabilitation or psychiatric distinct part unit of a CAH must meet all of the hospital conditions of participation and the criteria for exclusion from the inpatient PPS; these requirements will only apply to the services provided in the distinct part unit of a CAH and not the entire CAH.

Further, CMS proposes that, for CAHs that establish rehabilitation or psychiatric distinct part units, or both, in their facility, Medicare payment for inpatient services provided in those units would be made under the applicable existing payment methodology described below for inpatient rehabilitation facilities (IRFs) and inpatient psychiatric facilities (IPFs). Presently, IRFs are paid under a per discharge PPS that became effective for cost reporting periods beginning on or after January 1, 2002. At this time psychiatric hospitals and units that are excluded from the IPPS are paid for their inpatient operating costs on a reasonable cost basis, subject to a hospital-specific limit. However, as required by statute, a per diem PPS for Medicare payments for inpatient hospital services furnished in psychiatric hospitals and units was proposed by CMS in November 2003. The agency is in the process of developing the final rule for this proposed rule and when finalized, the IPF PPS will replace the reasonable cost based payment system currently in effect.

Waiver Authority for Designation of CAH as a Necessary Provider

Section 405(h) of the MMA adds language to the Social Security Act that terminates a State's authority to waive the location requirement for a CAH by designating the CAH as a necessary provider, effective January 1, 2006. Currently, a CAH is required to be located more than a 35-mile drive (or in the case of mountainous terrain or secondary roads, a 15-mile drive) from a hospital or another CAH, unless the CAH is certified by the State as a necessary provider of health care services to residents in the area. Under this provision, after January 1, 2006, States will no longer be able to designate a CAH based upon a determination it is a necessary provider of health care. In addition, the MMA included a grandfathering provision for CAHs that are certified as necessary providers prior to January 1, 2006. Under this provision, any CAH that is designated as a necessary provider in its State's rural health plan prior to January 1, 2006, will be permitted to maintain its necessary provider designation. The proposed rule revises the existing regulations to incorporate the MMA amendments.

Payment for Clinical Diagnostic Laboratory Tests

Medicare payment for clinical diagnostic laboratory tests provided to the outpatients of CAHs was established through the regulatory process and published in the *Federal Register* as part of the FY 2004 IPPS final rule published in August 2003. The CMS policy states that payment to a CAH for clinical diagnostic laboratory tests for outpatients is made on a reasonable cost basis only if the individuals for whom the tests are performed are outpatients of the CAH and are physically present at the CAH at the time specimens are collected. Otherwise, payment for these tests is made on a fee schedule basis. CMS notes that it published this final rule to clarify policy in this area and ensure that all relevant issues were publicly noted. Although the FY 2004 inpatient PPS final rule provides detail on the agency's logic, the FY 2005 proposed rule again addresses this issue with CMS stating its belief that extending reasonable cost payment in these instances is inconsistent with Medicare law and regulations and duplicates existing coverage and further, it creates confusion for beneficiaries and others by blurring the distinction between CAHs and other types of providers (for example, SNFs and HHAs) and increases the costs of providing care to Medicare patients without enhancing either the quality or the availability of that care.

Following publication of this policy in the FY 2004 inpatient PPS final rule, CMS continued to receive a number of letters and statements in CMS open door forums indicating that some commenters believe that this policy will impose a hardship on Medicare beneficiaries in rural areas. Several of these commenters argued that it might cause frail elderly nursing home patients to have to be moved to a CAH to have blood drawn or other specimen collection performed instead of sending a laboratory technician to the patient's bedside for the same purpose. Although CMS agreed with the commenters that this would not be an appropriate result, the agency noted that there are also alternative ways in which specimen collection and travel are payable under Medicare (for example, the laboratory benefit under Part B or home health agencies that have laboratory provider numbers). Therefore, the agency does not expect beneficiaries to face reduced access to services under this policy. However, in response to continuing claims of potential access problems, CMS invited the public to submit further, more specific comments that provide specific information on actual, rather than merely potential or anticipated access problems. In response, the agency states it received many communications asserting that these problems would occur, but no credible documentation that they actually are occurring. As a result of these responses, CMS is not proposing any further change in policy on this issue at this time but rather, is renewing its request for specific, verifiable documentation as to any actual access problems being generated by this policy, and will review carefully any such documentation received to determine whether current policy should be reconsidered.

Redefinition of Geographic Areas

Although the use of labor market areas is not an applicable concept for CAHs that are reimbursed at cost, CAHs should be aware of a proposal by CMS to redefine the labor markets used to determine the wage index. For the purpose of applying the Medicare wage index, CMS currently defines geographic areas using Metropolitan Statistical Areas (MSAs) based on 1990 census data. The Office of Management and Budget (OMB) released new definitions last summer based on the 2000 census. The OMB definitions replace MSAs with Core-Based Statistical Areas (CBSAs). Although CMS is not required to update the definitions for wage index areas using the more recent census data, the agency has proposed in the FY 2005 rule to adapt the new OMB definitions beginning October 1.

The result of this proposal is the creation of 49 new MSAs as well as significant reconfiguration of existing MSAs throughout the country. **Some hospitals with special rural status, such as sole community hospitals (SCHs), rural referral centers (RRCs), Medicare dependent hospitals (MDHs) or critical access hospitals (CAHs) would be reclassified from rural to urban under the new geographic definitions.** This proposed change affects 10 Iowa CAHs but CMS does not address this issue in the proposed rule so the impact of existing CAHs moving into an urban area is unknown at this time. See the attached map to identify the new CBSAs in Iowa.

NOTE: The revised regulations and interpretative guidelines for CAHs issued by CMS in late May address this issue in the standard for location in a rural area or treatment as rural [42 CFR 485.610(b)]. Specifically, the regulations require a CAH to meet the requirements of either of the items below:

1. The CAH meets the following:
 - a. The CAH is located outside any area that is a MSA, as defined by the OMB, or that has been recognized as urban per Medicare regulations;
 - b. The CAH is not deemed to be located in an urban area under Medicare regulations;
 - c. The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board, and is not among a group of hospitals that has been redesignated to an adjacent urban area under Medicare regulations.
2. The CAH is located within a MSA, as defined by the OMB, but is being treated as rural in accordance with 42 CFR 103 which allows hospitals that are located in urban areas to apply for

reclassification as rural. The request will be granted if the hospital meets any of the following conditions:

- a. The hospital is located in a rural census tract of a MSA as determined under the most recent version of the Goldsmith Modification as determined by the Office of Rural Health Policy.
- b. The hospital is located in an area designated by any law of regulation of the state in which it is located as a rural area, or the hospital is designated as a rural hospital by state law or regulation;
- c. The hospital would qualify as a rural referral center under Medicare regulations or a sole community hospital as set forth in Medicare regulations, if the hospital were located in a rural area.

It should be noted that one Iowa CAH that is located in an existing MSA successfully applied for, and received redesignation as rural based on the Goldsmith Modification described above. IHA's research of the Office of Rural Health Policy's material has revealed that the agency continues to use the list of metropolitan areas that was issued in 1999 while they study the 2000 census information. Therefore, each of the Iowa CAHs that will be located in a CBSA based on the OMB's 2000 census data as applied by CMS for Medicare payment purposes, will continue to meet the Goldsmith modification and should retain CAH status. However, IHA will closely monitor this situation and provide additional information as developments occur.

CAHs that choose to operate distinct part psychiatric or rehabilitation units under the provision addressed elsewhere in this document should be aware of the impact the new CBSAs will have on the Medicare wage index that is used in the determination of payments for these units. It is unclear whether the facility will receive the urban wage index from the area in which the CAH is located, or if the redesignation as rural for CAH purposes will require the rural Iowa wage index to be applied in these payment systems. IHA will seek clarification on this issue in the comment letter to CMS.

Special Circumstances of Hospitals Facing High Malpractice Insurance Rate Increases

CMS has received comments about the effects of rapidly escalating malpractice insurance premiums on hospital financial performance and continued access for Medicare beneficiaries to high quality inpatient hospital services. CMS acknowledges malpractice insurance premiums have increased at a high rate in some areas of the country during the last few years, but states the agency has no evidence that malpractice premiums have created issues of access to inpatient hospital services for Medicare beneficiaries. Therefore, CMS is inviting comments on the effect of increases in malpractice insurance premiums on hospitals participating in the Medicare program, and whether increasing malpractice costs may pose access problems for Medicare beneficiaries. Iowa CAHs experiencing rising medical practice premiums are encouraged to comment to CMS on specific experiences, although it is unclear from the agency's comments whether they are addressing this issue in the context of all hospitals, regardless of their Medicare payment status.